

EPA REGISTRATION NUMBER 2517-176
VOLUME 2

Arnold, Elyssa

From: Arnold, Elyssa
Sent: Monday, May 22, 2017 1:58 PM
To: Yanchulis, Michael
Subject: Confirmations of Request to Withdraw Applications for 2517-175 and 2517-176 - Refund request
Attachments: 2517-175 Withdrawal Confirmation.pdf; 2517-176 Withdrawal Confirmation.pdf

Hi Mick,

Please see attached withdrawal letters for the below PRIA actions. I believe just the first one will require a 75% refund since the second was only charged 25% initially. If you need any other information to start the refund process, please let me know. These are the first withdrawals I am handling so I may have missed something.

Thank you!
Elyssa

EPA Registration Number: 2517-176
Product Name: Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs
Decision Number: 527989
Fee Category: R340

EPA Registration Number: 2517-175
Product Name: Sergeant's Imidacloprid + Pyriproxyfen Spot On for Cats
Decision Number: 527990
Fee Category: R340.1

Kelly Hoskins
Manager of Regulatory Affairs
Sergeant's Pet Care Products, Inc.
10077 South 134th Street
Omaha, NE 68138-3710

Elyssa Arnold, Acting Product Manager 1
Invertebrate and Vertebrate Branch 3
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-0236
arnold.elyssa@epa.gov

From: Arnold, Elyssa
Sent: Monday, May 22, 2017 1:50 PM
To: 'Kelly Hoskins' <Kelly.Hoskins@perrigo.com>
Cc: Prince Bamaze <Prince.Bamaze@perrigo.com>
Subject: Confirmations of Request to Withdraw for 2517-175 and 2517-176

Hello Kelly,

Please see the attached letters confirming your request to withdraw the PRIA applications for 2517-175 and 2517-176.

Thank you,
Elyssa

Elyssa Arnold, Acting Product Manager 1
Invertebrate and Vertebrate Branch 3
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-0236
arnold.elyssa@epa.gov

From: Kelly Hoskins [<mailto:Kelly.Hoskins@perrigo.com>]
Sent: Friday, May 19, 2017 10:48 AM
To: Arnold, Elyssa <Arnold.Elyssa@epa.gov>
Cc: Prince Bamaze <Prince.Bamaze@perrigo.com>
Subject: RE: Deficiency letters for 2517-175 and 2517-176

Thank you.

Kelly Hoskins | Manager of Regulatory Affairs
Sergeant's Pet Care Products, Inc. dba Perrigo Animal Health
10077 South 134th Street
Omaha, NE 68138-3710
T: (402) 938-7079
E: kelly.hoskins@perrigo.com | perrigoanimalhealth.com

Quality Affordable Healthcare Products® for Pets!



From: Arnold, Elyssa [<mailto:Arnold.Elyssa@epa.gov>]
Sent: Friday, May 19, 2017 8:07 AM
To: Kelly Hoskins <Kelly.Hoskins@perrigo.com>
Cc: Prince Bamaze <Prince.Bamaze@perrigo.com>
Subject: RE: Deficiency letters for 2517-175 and 2517-176

Thank you, Kelly. I will start the refund process.

Elyssa

Elyssa Arnold, Acting Product Manager 1
Invertebrate and Vertebrate Branch 3
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Office of Pesticide Programs
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(703) 347-0236
arnold.elyssa@epa.gov



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 22, 2017

OPP Decision Number: 527989
EPA Registration Number: 2517-176
Product Name: Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs
EPA Receipt Date: 3/16/2017
EPA Company Number: 2517
Company Name: Sergeant's Pet Care Products, Inc.

Kelly Hoskins
Manager of Regulatory Affairs
Sergeant's Pet Care Products, Inc.
10077 South 134th Street
Omaha, NE 68138-3710

Subject: Confirmation of Request to Withdraw an Application

Dear Mr. Hoskins:

This is to confirm that the Agency has received and processed your request of 05/18/2017 to withdraw the above referenced application. Even when an application is withdrawn, the Agency must retain at least 25% of the fee pursuant to FIFRA Section 33(b)(2)(G). When an application is withdrawn within 60 days of the beginning of the PRIA review period, as is the case here, the Agency must refund 75% of the registration service fee. Accordingly, the Agency will refund the difference between what was paid and what the Agency must retain. In this case, the Agency will refund 75% of the registration service fee as soon as practical. Any future submission related to this action must be submitted as a new application that requires either the appropriate fee or payment of 25% or 50% of the fee with a request to waive the remaining 75% or 50%.

If you have questions concerning this letter, please contact the Pesticide Registration Fee Ombudsperson at (703) 308-9362.

Sincerely,

A handwritten signature in blue ink, appearing to read "Michael L. Goodis for".

Michael L. Goodis, Director
Registration Division
Office of Pesticide Programs

Arnold, Elyssa

From: Kelly Hoskins <Kelly.Hoskins@perrigo.com>
Sent: Monday, May 22, 2017 2:35 PM
To: Arnold, Elyssa
Subject: RE: Confirmations of Request to Withdraw for 2517-175 and 2517-176

Elyssa,
We have received the documents.

Kelly Hoskins | Manager of Regulatory Affairs
Sergeant's Pet Care Products, Inc. dba Perrigo Animal Health
10077 South 134th Street
Omaha, NE 68138-3710
T: (402) 938-7079
E: kelly.hoskins@perrigo.com | perrigoanimalhealth.com

Quality Affordable Healthcare Products® for Pets!



From: Arnold, Elyssa [mailto:Arnold.Elyssa@epa.gov]
Sent: Monday, May 22, 2017 12:50 PM
To: Kelly Hoskins <Kelly.Hoskins@perrigo.com>
Cc: Prince Bamaze <Prince.Bamaze@perrigo.com>
Subject: Confirmations of Request to Withdraw for 2517-175 and 2517-176

Hello Kelly,

Please see the attached letters confirming your request to withdraw the PRA applications for 2517-175 and 2517-176.

Thank you,
Elyssa

Elyssa Arnold, Acting Product Manager 1
Invertebrate and Vertebrate Branch 3
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-0236
arnold.elyssa@epa.gov

From: Kelly Hoskins [mailto:Kelly.Hoskins@perrigo.com]
Sent: Friday, May 19, 2017 10:48 AM
To: Arnold, Elyssa <Arnold.Elyssa@epa.gov>
Cc: Prince Bamaze <Prince.Bamaze@perrigo.com>
Subject: RE: Deficiency letters for 2517-175 and 2517-176

Thank you.

Kelly Hoskins | Manager of Regulatory Affairs
Sergeant's Pet Care Products, Inc. dba Perrigo Animal Health
10077 South 134th Street
Omaha, NE 68138-3710
T: (402) 938-7079
E: kelly.hoskins@perrigo.com | perrigoanimalhealth.com

Quality Affordable Healthcare Products® for Pets!



From: Arnold, Elyssa [<mailto:Arnold.Elyssa@epa.gov>]
Sent: Friday, May 19, 2017 8:07 AM
To: Kelly Hoskins <Kelly.Hoskins@perrigo.com>
Cc: Prince Bamaze <Prince.Bamaze@perrigo.com>
Subject: RE: Deficiency letters for 2517-175 and 2517-176

Thank you, Kelly. I will start the refund process.

Elyssa

Elyssa Arnold, Acting Product Manager 1
Invertebrate and Vertebrate Branch 3
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-0236
arnold.elyssa@epa.gov

From: Kelly Hoskins [<mailto:Kelly.Hoskins@perrigo.com>]
Sent: Thursday, May 18, 2017 3:37 PM
To: Arnold, Elyssa <Arnold.Elyssa@epa.gov>
Cc: Prince Bamaze <Prince.Bamaze@perrigo.com>
Subject: RE: Deficiency letters for 2517-175 and 2517-176

Elyssa,
Here are our withdrawal letters, please let me know if you any additional questions.

Kelly Hoskins | Manager of Regulatory Affairs
Sergeant's Pet Care Products, Inc. dba Perrigo Animal Health
10077 South 134th Street
Omaha, NE 68138-3710
T: (402) 938-7079

E: kelly.hoskins@perrigo.com | perrigoanimalhealth.com

Quality Affordable Healthcare Products® for Pets!



From: Arnold, Elyssa [<mailto:Arnold.Elyssa@epa.gov>]
Sent: Thursday, May 18, 2017 1:50 PM
To: Kelly Hoskins <Kelly.Hoskins@perrigo.com>
Subject: RE: Deficiency letters for 2517-175 and 2517-176

Hello Kelly,

Just checking back in with you on these PRIA actions. Are you planning to withdraw the applications?

Thanks,
Elyssa

Elyssa Arnold, Acting Product Manager 1
Invertebrate and Vertebrate Branch 3
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-0236
arnold.elyssa@epa.gov

From: Arnold, Elyssa
Sent: Wednesday, May 10, 2017 12:12 PM
To: 'Kelly Hoskins' <Kelly.Hoskins@perrigo.com>
Subject: Deficiency letters for 2517-175 and 2517-176

Mr. Hoskins,

Please see the attached deficiency letters in regards to your recent applications for 2517-175 and 2517-176, as we discussed via phone yesterday. Let me know if you have any questions.

Regards,
Elyssa

Elyssa Arnold, Acting Product Manager 1
Invertebrate and Vertebrate Branch 3
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-0236
arnold.elyssa@epa.gov

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 9, 2017

OPP Decision Number: 527989
EPA Registration Number: 2517-176
Product Name: Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs
EPA Receipt Date: 3/16/2017
EPA Company Number: 2517
Company Name: Sergeant's Pet Care Products, Inc.

Kelly Hoskins
Manager of Regulatory Affairs
Sergeant's Pet Care Products, Inc.
10077 South 134th Street
Omaha, NE 68138-3710

Dear Mr. Hoskins:

The Agency has completed its preliminary technical screening of your application pursuant to Section 33(f)(4)(B)(i)(II) of the Federal Insecticide, Fungicide, and Rodenticide (FIFRA) Act, as amended by the Pesticide Registration Improvement Extension Act. The Agency has determined that your application has not passed the preliminary technical screen and therefore is subject to rejection if the application is not corrected.

Specifically, the changes proposed for the basic formulation cannot be supported by the currently cited acute toxicity data. The proposed changes are substantial and require a new product registration.

In order for the review of your product to continue, you will need to correct your application to address the item(s) listed above within 10 business days of the date you received this letter. Corrections must be received by EPA by the 10th business day. EPA recommends sending your complete set of corrections by email to the contact listed below to ensure they are timely received. If studies or confidential information are being submitted by mail, a complete courtesy copy, minus confidential information, received by email by the deadline will be considered timely. If you cannot correct the application or do not respond within 10 business days, your application will be rejected.

At this time you could also choose to withdraw your application. If you have questions, please contact Elyssa Arnold at arnold.elyssa@epa.gov or 703-347-0236.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael L. Goodis", with a stylized flourish at the end.

Michael L. Goodis, Director
Registration Division
Office of Pesticide Programs

Arnold, Elyssa

From: Arnold, Elyssa
Sent: Wednesday, May 10, 2017 12:12 PM
To: 'Kelly Hoskins'
Subject: Deficiency letters for 2517-175 and 2517-176
Attachments: 2517-175 10day letter 20170509.pdf; 2517-176 10day letter 20170509.pdf

Mr. Hoskins,

Please see the attached deficiency letters in regards to your recent applications for 2517-175 and 2517-176, as we discussed via phone yesterday. Let me know if you have any questions.

Regards,
Elyssa

Elyssa Arnold, Acting Product Manager 1
Invertebrate and Vertebrate Branch 3
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-0236
arnold.elyssa@epa.gov



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Note to File

~~Contains Confidential Business Information Do not release~~

Date: May 10, 2017

Registration Number: 2517-175 & 2517-176

Decision Number: 527990, 527989

PM/RM Name: Marianne Lewis, Biologist

Background: The registrant cited studies from Bayer (11556-125) to support the registration of their products when they were registered initially. The two products have the same formulation: one is for cats (-175) and one is for dogs (-176). It was determined that 2517-175 & -176 are substantially similar to the 11556-125. Therefore, the tox profile assigned to both products is as follows: acute oral – III, acute dermal – IV, acute inhalation – IV (waived), primary eye irritation – III, primary skin irritation – IV, and is classified as a non sensitizer.

The registrant (Sergeant's) submitted under the 6(a)2 data requirement, a new primary eye irritation study that was conducted on the 2517-175 cat product. The test material used in the 6(a)2 was confirmed to be reflective of the Basic CSF dated 3/2/15 (substantially similar to 11556-125). This study also applied to the 2517-176 product – same formulation but for dogs. The primary eye irritation study was classified as a Tox Category II. So, this new tox category caused the Signal Word to change from Caution to Warning along with required change in language for the HHDA. The Agency informed the registrant of the results and submitted new labels with the required changes – each were stamped acceptable on 3/30/17.

The registrant now wishes to revise the Basic CSF – [REDACTED]

[REDACTED] After comparing the new proposed CSF to the CSF from 11556-125, it was determined that the acute tox studies conducted on the 11556-125 would no longer support the new formulation - this is a new product – totally different from the originally registered product. The registrant was informed, during a conference call on 5/9/17, that if they wanted to keep this new Basic CSF they would have to come in with it as a new product, with new acute tox and CRP. I told them that they could request the acute inhalation waiver again and that a new skin sensitization study was probably not necessary (same inerts just different amounts – no need to waste animals). The only option available for the registrant is to withdraw the proposed CSF, the registrant said they wanted to think about it.

Inert ingredient information may be entitled to confidential treatment



Receipt for Section 3

S: 1000727

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Print Letter

Application Type: Amendment

Fee For Service: ☐ Yes ☒ No

Enter More Information

Billable: ☒ Yes ☐ No

Tracking

Company: 2517 SERGEANT'S PET CARE PRODUCTS, INC.

V

Risk Manager: Registration Division, Risk Management Team 1

Product #: 2517-176

Product Name: Sergeant's Imidacloprid + Pyriproxyfen Squeez

Override#:

Me Too

Section3:

Me Too Product

Name:

Application Date: 15-Mar-2017



OPP Rec'd Date: 16-Mar-2017



Front End Date: 16-Mar-2017



Risk Manager Send Date:



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

AMENDMENT WITH STUDIES

Receipt Content

De

Study

CSF

View/Edit

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Sergeant's Pet Care Products, Inc.
10077 South 134th Street
Omaha, NE 68138-3710

CONTACT PERSON (Return to)

Kelly R. Hoskins
Sergeant's Pet Care Products, Inc.
10077 South 134th Street
Omaha, NE 68138-3710

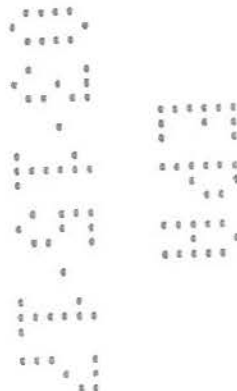
REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

PRIA amendment for the end-use products, Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Cats (EPA Reg. No. 2517-175), and Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs (EPA Reg. No. 2517-176), to revise the Confidential Statement of Formula.

SUBMITTAL DATE:

March 15, 2017

Volume	Study Title	MRID No.
	Administrative	NA
1	Imidacloprid + Pyriproxyfen Spot on for Dogs and Cats: Primary Eye Irritation Study in Rabbits (Study Number 44516)	50217601



FAST-TRACK AMENDMENTS – Completeness Screening Checklist

Expert's In-Processing Signature: L. Patel

Date: 4/21/17 PM #: 1

EPA Reg. Number: <u>2517-176</u>		EPA Receipt Date: <u>4/19/17</u>		
	Checklist Item	Yes	No	N/A
1	Application Form (EPA Form 8570-1) - signed?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Confidential Statement of Formula (EPA Form 8570-29) - signed?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
3	Certification with Respect to Citation of Data (EPA Form 8570-34) - signed?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
4	Formulator's Exemption Statement (EPA Form 8570-27) - signed?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5	Data Matrix (EPA Form 8570-35) [Applicable for adding me-too uses] - signed?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	a) Selective Method?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	b) Cite-All Method?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	c) Public copy of Matrix provided? See PR Notice 98-5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	Is Label included? (5 copies)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	a) Electronic Label submitted?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Comments:				

S: 1002396

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: Amendment

Fee For Service: ☐ Yes ☒ No

Billable: ☐ Yes ☒ No

Company: 2517 SERGEANT'S PET CARE PRODUCTS, INC.

V

Print Letter

Enter More Information

Tracking

Risk Manager: Registration Division, Risk Management Team 1

Product #: 2517-176

Product Name: Sergeant's Imidacloprid + Pyriproxyfen Squeez

Override#:

Me Too

Me Too Product

Section3:

Name:

Application Date: 10-Apr-2017

OPP Rec'd Date: 19-Apr-2017

Front End Date: 19-Apr-2017

Risk Manager Send Date: 20-Apr-2017

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

AMENDMENT

Receipt Content

Paper Label

Des

View/Edit

Form A: ☐

Signature Date:

Form B: ☐

New Ingredient:

Request Date:

New Ingredient:

Received Date:

Signature Date:



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 20, 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MR. PRINCE M. BAMAZE
SERGEANT'S PET CARE PRODUCTS, INC.
PO Box 540399
OMAHA, NE 68154-0399

PRODUCT NAME: Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs
COMPANY NAME: SERGEANT'S PET CARE PRODUCTS, INC.
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 2517-176
EPA RECEIPT DATE: 04/19/17

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 1, at (703) 308-8045.

Sincerely,

A handwritten signature in black ink, appearing to be "S. [unclear]", is written over the word "Sincerely,".

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division



Fee for Service {1002396U~

This package includes the following

- ☐ New Registration
- ☒ Amendment

- ☐ Studies? ☐ Fee Waiver?
- ☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 1

Receipt No.

S- 1002396

EPA File Symbol/Reg. No.

2517-176

Pin-Punch Date:

4/19/2017



This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$ _____

Parent/Child Decisions:


☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: L. Patel

Date: 4/20/17

Remarks:

EPA United States Environmental Protection Agency Washington, DC 20460		<input type="checkbox"/> Registration <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide - Section I			
1. Company/Product Number 2517-176		2. EPA Product Manager Venus Eagle	
4. Company/Product (Name) Sergeant's Pet Care Products, Inc./Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Sergeant's Pet Care Products, Inc. 10077 South 134 th Street Omaha, NE 68138-3710 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to: EPA Reg. Nos. _____ Product Name _____	
Section II			
<input checked="" type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated XX-XX-XX <input type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated XX-XX-XX <input type="checkbox"/> "Me Too" Application <input type="checkbox"/> Other - Explain below.	
Explanation: Use additional page(s) if necessary. (For section I and Section II.)			
Submission of revised label in association with EPA Receipt number assigned: 1000727; EPA receipt date: 03/16/2017. Formulation amendment for the end-use product, containing Imidacloprid (9.1%) and Pyriproxyfen (0.46%) for dogs.			
Section III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No *Certification must be submitted	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. 0.014 fl oz (0.4 ml) 0.034 fl oz (1.0 ml) 0.085 fl oz (2.5 ml) 0.135 fl oz (4.0 ml)	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. No. per Container 1, 2, 3, 4, 5, 6, 12, 24, 50, 75, 100 vials	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) Plastic Bag
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container Various (see above)	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		5. Location of Label Directions <input type="checkbox"/> On Can <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Other Printed box			
Section IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)			
Name James B. Messina		Title Authorized Representative	
		Telephone No. (Include Area Code) (202) 772-4832	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature BY: 		3. Title Manager of Regulatory Affairs	
4. Typed Name: Kelly R. Hoskins		5. Date: April 10, 2017	



Sergeant's Pet Care Products, Inc.

10077 South 134th Street • Omaha, NE 68138- 3710 • Telephone 402.938.7000 • Fax 402.938.7091 • www.sergeants.com

April 19, 2017

Venus Eagle, PM1
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk (AMEND)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

SUBJECT: *Amended Label Associated with EPA Receipt No: 1000727; and
EPA Receipt Date: 03/16/2017
Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs,
EPA Registration Number 2517-176*

Dear Ms. Eagle:

Sergeant's Pet Care Products, Inc. (EPA Company Number 2517) is submitting an amended label for the subject product in association with the recently submitted application for pesticide amendment to revise the Confidential Statement of Formula on March 15, 2016 (EPA Receipt No: 1000727; EPA Receipt Date: 03/16/2017). Please note that the data citation submitted with the amendment supports the label revision.

Briefly, the amended label was omitted from the submission in error. Submission of the label at this time is not expected to delay the Agency's review of the R340.1 amendment package.

Please find the following documents enclosed for the *Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs*, EPA Registration Number 2517-176:

- Application for Pesticide Amendment (EPA Form 8750-1);
- Master Label dated April 10, 2017 (highlighted and "clean" versions); and
- EPA stamped label dated March 30, 2017 (for Agency's reference).

If you have any questions regarding this submission, please contact me at 402-938-7079 or khoskins@sergeants.com.

Sincerely,

Kelly R. Hoskins
Manager of Regulatory Affairs

enclosures

21-Day Screen of Amendment
(Completed by Contractor)

21-day Expires on 4-6-17

Document Part Of: 2517-176
MRID, If Any: 502176

Content Screen: Recommended to
Pass/Fail

11-3 Review: Passed/Failed/NA

Overall Status: Pass/Fail

Document returned to:

ASWATHY BALAN

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 3-16-17

Experts In-Processing Signature: B.B.

Date 4-7-17

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>2517-176</u>		EPA Receipt Date: <u>3-16-17</u>	
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Items for Review	Yes	No	N/A*
1 Application Form (EPA Form 8570-1) signed & complete including package type	X		
2 Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)	X		
<div style="display: flex; justify-content: space-between;"> <div style="width: 60%;">a) All <u>inerts</u>, including fragrances, approved for the proposed uses (see Footnote A)</div> <div style="width: 10%;">yes</div> <div style="width: 10%;">no</div> </div>	X		
3 Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)	X		
Certificate and data matrix consistent	X		
<div style="display: flex; justify-content: space-between;"> <div style="width: 60%;">If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)</div> <div style="width: 10%;">yes</div> <div style="width: 10%;">no</div> </div>			
If applicable, is there a letter of Authorization for exclusive use only.			
4 Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)	X		
5 Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)	X		
<div style="display: flex; justify-content: space-between;"> <div style="width: 60%;">a) Selective Method (Fee category experts use)</div> <div style="width: 10%;">yes</div> <div style="width: 10%;">no</div> </div>	X		
b) Cite-All (Fee category experts use)			
c) Applicant owns all data (Fee category experts use)			
6 5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)			X
7 Is the data package consistent with PR Notice 86-5	X		
8 Notice of Filing included with petitions			X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments:

Documentation: Pass
 - Required forms are complete

Related Reg No.
 2517-175

Inerts: Pass
 - Inerts approved for Non-Food Use

PRN 11-3: Pass
 - MRID: 502176

Overall Status: Pass
 sm 4/20/17

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 6, 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-527989
EPA File Symbol or Registration Number: 2517-176
Product Name: Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs
EPA Receipt Date: 16-Mar-2017
EPA Company Number: 2517
Company Name: SERGEANT'S PET CARE PRODUCTS, INC.

KELLY HOSKINS
SERGEANT'S PET CARE PRODUCTS, INC.
PO BOX 540399
OMAHA, NE 68154-0399

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R340

AMENDMENT;NON-FAST TRACK;REVIEW WITHIN RD, E.G. PRECAUTIONARY LABELING;

No additional payment is due at this time. If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 347-0510.

Sincerely,

A handwritten signature in blue ink, appearing to be "JDR", is written over the word "Sincerely,".

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{1000727>~

This package includes the following

- ☐ New Registration
- ☒ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr.

Receipt No.

S-

EPA File Symbol/Reg. No.

Pin-Punch Date:

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Margan K. M

Date: 3/20/17

Remarks:



Receipt for Section 3

S: 1000727

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Print Letter

Application Type: Amendment

Fee For Service: ☐ Yes ☒ No

Enter More Information

Billable: ☒ Yes ☐ No

Tracking

Company: 2517 SERGEANT'S PET CARE PRODUCTS, INC.

V

Risk Manager: Registration Division, Risk Management Team 1

Product #: 2517-176 Product Name: Sergeant's Imidacloprid + Pyriproxyfen Squeez

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 15-Mar-2017

OPP Rec'd Date: 16-Mar-2017

Front End Date: 16-Mar-2017

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

AMENDMENT WITH STUDIES

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Receipt Content

Study

CSF

View/Edit

Your payment has been submitted to Pay.gov and the details are below. To confirm that the payment processed as expected, you may refer to your bank statement on the scheduled payment date. If you have any questions or wish to cancel this payment, you will need to contact the agency you paid at your earliest convenience.


Application Name: PRIA Service Fees
Pay.gov Tracking ID: 26059UPH
Agency Tracking ID: 75191734999

Account Holder Name: Sergeants Pet Care Products Inc
Transaction Type: ACH Debit
Transaction Amount: \$4,985.00
Payment Date: 02/27/2017
Account Type: Business Checking
Routing Number: 121100782
Account Number: *****0100

Transaction Date: 02/24/2017 09:02:40 AM EST
Total Payments Scheduled: 1
Frequency: OneTime

Registration Number: 2517-175, 2517-176
Company Name: SERGEANT'S
Company Number: 2517
Action Code: R340

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

EPA United States Environmental Protection Agency Washington, DC 20460		<input type="checkbox"/> Registration <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Other	OPD Identifier Number
Application for Pesticide - Section I			
1. Company/Product Number 2517-176		2. EPA Product Manager Venus Eagle	
4. Company/Product (Name) Sergeant's Pet Care Products, Inc./Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Sergeant's Pet Care Products, Inc. 10077 South 134 th Street Omaha, NE 68138-3710 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to: EPA Reg. Nos. _____ Product Name _____	
Section II			
<input checked="" type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated XX-XX-XX <input type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated XX-XX-XX <input type="checkbox"/> "Me Too" Application <input type="checkbox"/> Other - Explain below.	
Explanation: Use additional page(s) if necessary. (For section I and Section II.) Sergeant's Pet Care Products, Inc. is submitting a formulation amendment for the end-use product containing Imidacloprid (9.1%) and Pyriproxyfen (0.46%) for dogs. Sergeant's requests that the Agency review the amendment as a 4 month PRIA timeframe under R340.			
Section III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No *Certification must be submitted	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. 0.014 fl oz (0.4 ml) 0.034 fl oz (1.0 ml) 0.085 fl oz (2.5 ml) 0.135 fl oz (4.0 ml)	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. No. per Container 1, 2, 3, 4, 5, 6, 12, 24, 50, 75, 100 vials	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) Plastic Bag
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container Various (see above)	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Other Printed box <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		5. Location of Label Directions <input type="checkbox"/> On Can <input checked="" type="checkbox"/> On Labeling accompanying product	
Section IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name James B. Messina		Title Authorized Representative	
		Telephone No. (Include Area Code) (202) 772-4932	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature BY: 		3. Title Manager of Regulatory Affairs	
4. Typed Name: Kelly R. Hoskins		5. Date: March 15, 2017	

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Sergeant's Pet Care Products, Inc.
10077 South 134th Street
Omaha, NE 68138-3710

CONTACT PERSON (Return to)

Kelly R. Hoskins
Sergeant's Pet Care Products, Inc.
10077 South 134th Street
Omaha, NE 68138-3710

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

PRIA amendment for the end-use products, Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Cats (EPA Reg. No. 2517-175), and Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs (EPA Reg. No. 2517-176), to revise the Confidential Statement of Formula.

SUBMITTAL DATE:

March 15, 2017

Volume	Study Title	MRID No.
	Administrative	NA
1	Imidacloprid + Pyriproxyfen Spot on for Dogs and Cats: Primary Eye Irritation Study in Rabbits (Study Number 44516)	



United States
Environmental Protection Agency
 Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address Sergeant's Pet Care Products, Inc. 10077 South 134th Street Omaha, NE 68138-3710	EPA File Symbol/Registration Number 2517-176
	Product Name Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs
	Date of Confidential Statement of Formula (EPA Form 8570-4) 3/1/2017

As an authorized representative of the applicant for registration of the product identified above, I certify that:

- (1) This product contains the following active ingredient(s):

Imidacloprid, Pyriproxyfen

- (2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

- (3) Indicate by checking (A) or (B) below which paragraph applies:

- ☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

- ☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

- (4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
<div style="background-color: black; width: 100%; height: 100px;"></div>		
Signature <i>Kelly R. Hoskins</i>	Name and Title Kelly R. Hoskins, Manager of Regulatory Affairs	Date 3/1/2017

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 – EPA
 Copy 2 – Applicant copy



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710	EPA Registration Number/File Symbol 2517-176
Active Ingredient(s) and/or representative test compound(s) Imidacloprid, Pyriproxyfen	Date 2/23/2017
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor non-food	Product Name Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
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SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>Kelly R. Hoskins</i>	Date 2/23/2017	Typed or Printed Name and Title Kelly R. Hoskins, Manager of Regulatory Affairs
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX


Date: March 15, 2017	EPA Reg No./File Symbol: 2517-176	Page 1 of 4
Applicant's/Registrant's Name & Address Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710	Product: Sergeant's® Imidacloprid + Pyriproxyfen Squeeze On for Dogs	

Ingredients: Imidacloprid, Pyriproxyfen

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry					
830.1550, 830.1600, 830.1620, 830.1650, 830.1670, 830.1750	Group A Product Chemistry for Sergeant's Imidacloprid + Pyriproxyfen Spot On Products	49510301	Sergeant's Pet Care Products	OWN	
830.1800	Analytical Method for Sergeant's Imidacloprid + Pyriproxyfen Spot On Products	49510302	Sergeant's Pet Care Products	OWN	
830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.6315, 830.6316, 830.6319, 830.6321, 830.7000, 830.7100, 830.7300, 830.7520	Group B Product Chemistry and Waivers for Sergeant's Imidacloprid + Pyriproxyfen Spot On Products	49510303	Sergeant's Pet Care Products	OWN	
830.6302, 830.7100, 830.7300	Physical and Chemical Characteristics: Color, Viscosity, and Density for Sergeant's Imidacloprid + Pyriproxyfen Spot On Products	49510304	Sergeant's Pet Care Products	OWN	
830.6317, 830.6320	Accelerated 14-Day Storage Stability and Corrosion Characteristics of Sergeant's Imidacloprid + Pyriproxyfen Spot On Products	49510305	Sergeant's Pet Care Products	OWN	
830.6315	Flashpoint for Sergeant's 9.1% Imidacloprid and 9.1% Imidacloprid + 0.46% Pyriproxyfen Spot-on Products	49469206	Sergeant's Pet Care Products	OWN	

Toxicology Data Requirements

870.1100	Acute Oral Toxicity Up and Down Procedure with CVSG 003	49510307	Sergeant's Pet Care Products	OWN	
870.1100	Acute Oral Toxicity Study with Imidacloprid (9.1%)/Pyriproxyfen (0.9%) Spot On	45096904	Bayer Animal Health	OLD	
870.1200	Acute Dermal Toxicity Study with Imidacloprid (9.1%)/Pyriproxyfen (0.9%) Spot On	45096905	Bayer Animal Health	PAY	
870.1300	Waiver Request of Requirement for Further Testing for Acute Inhalation Toxicity for the Following Sergeant's Products: Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs, Sergeant's Imidacloprid + Pyriproxyfen Spot On for Cats	49510306	Sergeant's Pet Care Products	OWN	


Signature 	Name and Title Kelly R. Hoskins, Manager of Regulatory Affairs	Date 3/15/2017
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX


Date: March 15, 2017		EPA Reg No./File Symbol: 2517-RTA		Page 2 of 4	
Applicant's/Registrant's Name & Address Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710		Product: Sergeant's® Imidacloprid + Pyriproxyfen Squeeze On for Dogs			
Ingredients: Imidacloprid, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2400	Primary Eye Irritation Study with Imidacloprid (9.1%)/Pyriproxyfen (0.9%) Spot On	45096907	Bayer Animal Health	PAY	
870.2400	Imidacloprid + Pyriproxyfen Spot on for Dogs and Cats: Primary Eye Irritation in Rabbits, Report 43661	50167801	Sergeant's Pet Care Products	OWN	
870.2500	Primary Dermal Irritation Study with Imidacloprid (9.1%)/Pyriproxyfen (0.9%) Spot On	45096908	Bayer Animal Health	PAY	
870.2600	Dermal Sensitization Study with Imidacloprid (9.1%)/Pyriproxyfen (0.9%) Spot On	45096909	Bayer Animal Health	PAY	
870.7200	Evaluation of the General Safety of 9.1% Imidacloprid with 0.9% Pyriproxyfen Spot On Formulation in the Target Species, Seven Week Old Puppies	45097101	Bayer Animal Health	PAY	
870.7200	Evaluation of the General Safety of 9.1% Imidacloprid with 0.9% Pyriproxyfen Spot On Formulation in the Target Species, Adult Dogs	45097102	Bayer Animal Health	PAY	
870.7200	Acute Toxicity Evaluation for Dermal Treatment of Dogs with Imidacloprid (Bay t 7391) Spot-on: Lab Project Number: 74580: TR-94D-010. Unpublished study prepared by Miles Inc. 19 p.	43679607	Bayer Animal Health	OLD	
870.7200	General Safety Evaluation for Topical Use of Imidacloprid (Bay t 7391) Spot-On On Dogs: Lab Project Number: 74590: TR-95D-005. Unpublished study prepared by Bayer Corp. 40 p.	43679608	Bayer Animal Health	OLD	
870.7200	General Safety Evaluation for Topical Use of Imidacloprid (Advantage) Spot-On on Puppies: Lab Project Number: TR-96D-003: 74730: 10332. Unpublished study prepared by Bayer Corp. 47 p.	44099801	Bayer Animal Health	OLD	
870.7200	Acute Oral Toxicity Evaluation of Imidacloprid (Advantage) in Dogs: Lab Project Number: TR-96D-010: 74764: J:USERS\LINDA\NOREPORT\JAS0171.RPT. Unpublished study prepared by Bayer Corp.. Animal Health. 10 p.	44179801	Bayer Animal Health	OLD	
Pyriproxyfen Generic Data for Companion Animal Use					
NA	Evaluation of the Toxicology and Potential Health Risks Associated with Indoor, Nonfood Uses of Sumilarv: Unpublished study prepared by Technology Services Group, Inc. 71 p.	42182701	McLaughlin Gormley King Company	OLD	
870.3200	S31183: Toxicity Study by Oral (Capsule) Administration to Beagle Dogs for 52 Weeks (Sumilarv Technical Grade): Unpublished study prepared by Life Science Research Ltd. 320 p.	42178309	McLaughlin Gormley King Company	OLD	
Signature 		Name and Title Kelly R. Hoskins, Manager of Regulatory Affairs		Date 3/15/2017	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX


Date: March 15, 2017		EPA Reg No./File Symbol: 2517-RTA		Page 3 of 4	
Applicant's/Registrant's Name & Address Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710		Product: Sergeant's® Imidacloprid + Pyriproxyfen Squeeze On for Dogs			
Ingredients: Imidacloprid, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Performance Test Guidelines					
810.3300	Efficacy Evaluation of Bay t 7391 (Imidacloprid) 10% Solution Applied Dermal for Control of Fleas on Dogs	43679609	Bayer Animal Health	OLD	
810.3300	Efficacy Confirmation of NTN 33893 (Imidacloprid) Solution Applied Dermal for Control of Fleas on Dogs	43679610	Bayer Animal Health	OLD	
810.3300	A Controlled Randomised Study to Evaluate the Efficacy of Advantage Against a Natural Infestation of Dog Lice (Trichodectes canis) Following a Single Topical Administration to Adult Mixed Breed Dogs	47190401	Bayer Animal Health	PAY	
810.3300	Comparative Evaluation of How Quickly Advantage and Frontline (Fipronil) Top Spot Kill Fleas on Dogs: (final Report)	44256901	Bayer Animal Health	OLD	
810.3300	Imidacloprid Topical Formulation: Larvicidal Effect Against Ctenocephalides felis in the Surroundings of Treated Dogs	44256902	Bayer Animal Health	OLD	
810.3300	Evaluation of the Effects of Shampooing or Water Immersion on the Initial and Residual Efficacy of Advantage for Flea Control on Dogs	44256903	Bayer Animal Health	OLD	
810.3300	Nylar 50 (percent) Concentrate: Product Performance/Efficacy Reports. Unpublished study prepared by McLaughlin Gormley King. 79 p.	45086801	McLaughlin Gormley King Company	PAY	
Signature 		Name and Title Kelly R. Hoskins, Manager of Regulatory Affairs		Date 3/15/2017	



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DATA MATRIX

Date: March 15, 2017		EPA Reg No./File Symbol: 2517-RTA		Page 4 of 4	
Applicant's/Registrant's Name & Address Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710		Product: Sergeant's® Imidacloprid + Pyriproxyfen Squeeze On for Dogs			
Ingredients: Imidacloprid, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Child Resistant Packaging					
40 CFR Part 157.32	Evaluation of the Dog Squeeze On 0.67 ml White Applicator with Orange Label Indicator (1x), scissors to open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48614202	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the Dog Squeeze On 1.34 ml White Applicator with Green Label Indicator (1x), scissors to open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48614203	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the Dog Squeeze On 2.68 ml White Applicator with Red Label Indicator (1x), scissors to open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48614204	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the Dog Squeeze On 4.02 ml White Applicator with Blue Label Indicator (1x), scissors to open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48614205	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the Dog Squeeze On 0.67ml White Applicator with Orange Label Indicator (3x), scissors to open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48059803	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the Dog Squeeze On 1.34ml White Applicator with Green Label Indicator (3x), scissors to open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48059804	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the Dog Squeeze On 2.68ml White Applicator with Red Label Indicator (3x), scissors to open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48059805	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the Dog Squeeze On 4.02ml White Applicator with Blue Label Indicator (3x), scissors to open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48059806	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Use of One Tube 1x Child Resistant Unit Packaging Data (Child and Senior) to Support All Unit Configurations for Fipronil Based Spot-On Registrations	48614201	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the Cat Squeeze On 0.5ml White Applicator with Purple Label Indicator (3x), scissors to open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48650101	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Amended Report: Evaluation of the Cat Squeeze On 0.5ml White Applicator with Purple Label Indicator (3x), scissors to open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48279601	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the Cat Squeeze On 0.5ml White Applicator with Purple Label Indicator (1x), scissors to open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48613701	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the One Count Dog & Cat Squeeze On White Tube, 0.2 ml fill with no label as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.		Sergeant's Pet Care Products, Inc.	OWN	
Signature 		Name and Title Kelly R. Hoskins, Manager of Regulatory Affairs		Date 3/15/2017	

PROCESSING REQUEST

Reg # 75A-176 Decision # 526845

Description: LABEL AMEND

Material Available Electronically (see PPLS):

☒ Electronic Label/Letter Dated

3/30/17

☐ Other:

Material Sent (see jacket):

☐ Stamped Label/Letter Dated

☐ Notification Dated

☐ New CSF(s) Dated

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: McGee

Division: RD

Phone: 308-8043

Date: 3/30/17



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 30, 2017

Kelly Hoskins
Manager of Regulatory Affairs
Sergeant's Pet Care Products, Inc.
dba Perrigo Animal Health
10077 South 134th Street
Omaha, NE 68138-3710

Subject: Label Amendment – Revising label language to reflect changes due to 6(a)2
primary eye irritation study results
Product Name: Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs
EPA Registration Number: 2517-176
Application Date: 1/24/2017
Decision Number: 526845

Dear Mr. Hoskins:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. The next label printing of this product must use this labeling unless subsequent changes have been approved. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Marianne Lewis by phone at (703) 308-8043 or via email at lewis.marianne@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Elyssa Arnold". The signature is written in a cursive style with a large, stylized "A".

Elyssa Arnold, Acting Product Manager 01
Invertebrate & Vertebrate Branch 3
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

Sergeant's® Master Label

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Information in { } is note to reviewer.

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FRONT PANEL

Dogs Squeeze On Imidacloprid + Pyriproxyfen

[Optional text appears in brackets/parenthesis – the final label may include some or all of the optional text on front, back or side label panels]

Sergeant's® Imidacloprid + Pyriproxyfen Squeeze On for Dogs

{Market Label-the word Dog will be at least 40-75% in height of the largest letter in the primary brand name.}

{Market Label-a large clear picture of a dog in the respective weight range will be on the front panel of the label for the product as packaged.}

{One of the following statements will appear on appropriate weight band market label on front panel as required per Agency's pet spot-on mitigation measures:}

For use ONLY on dogs [[&][and] puppies] [weighing] 3 [-][to] 10 lbs. and over 7 weeks [old][of age] {0.4 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] 3 [-][to] 10 lbs. and 7 weeks [of age] or older {0.4 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] 11 [-][to] 20 lbs. and over 7 weeks [old][of age] {1.0 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] 11 [-][to] 20 lbs. and 7 weeks [of age] or older {1.0 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] 21 [-][to] 55 lbs. and over 7 weeks [old][of age] {2.5 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] 21 [-][to] 55 lbs. and 7 weeks [of age] or older {2.5 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] [more than][over][>] 55 lbs. and over 7 weeks [old][of age] {4.0 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] [more than][over][>] 55 lbs. and 7 weeks [of age] or older {4.0 ml size package}

ONLY for dogs [[&][and] puppies]] over 7 weeks [old][of age]] and [weighing] 3 [-][to] 10 lbs. {0.4 ml size package}

ONLY for dogs [[&][and] puppies]] 7 weeks [of age] or older and [weighing] 3 [-][to] 10 lbs. {0.4 ml size package}

ONLY for dogs [[&][and] puppies]] over 7 weeks [old][of age]] and [weighing] 11 [-][to] 20 lbs. {1.0 ml size package}

ONLY for dogs [[&][and] puppies]] 7 weeks [of age] or older and [weighing] 11 [-][to] 20 lbs. {1.0 ml size package}

ONLY for dogs [[&][and] puppies]] over 7 weeks [old][of age]] and [weighing] 21 [-][to] 55 lbs. {2.5 ml size package}

ONLY for dogs [[&][and] puppies]] 7 weeks [of age] or older and [weighing] 21 [-][to] 55 lbs. {2.5 ml size package}

ONLY for dogs [[&][and] puppies]] over 7 weeks [old][of age]] and [weighing] [more than][over][>] 55 lbs. {4.0 ml size package}

ONLY for dogs [[&][and] puppies]] 7 weeks [of age] or older and [weighing] [more than][over][>] 55 lbs. {4.0 ml size package}

[1.5cm x 1.5cm on final]



DO NOT
USE ON
CATS

ACCEPTED

03/30/2017

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for a pesticide registered under EPA Reg. No. 2517-176

Sergeant's® Master Label

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{following text will be in addition to the above required language}

Small Dogs {only for use on label for 3-10 lbs and 7 weeks or older product}

Medium Dogs {only for use on label for 11-20 lbs and 7 weeks or older product}

Large Dogs {only for use on label for 21-55 lbs and 7 weeks or older product}

Extra Large Dogs {only for use on label for >55 lbs and 7 weeks or older product}

ACTIVE INGREDIENTS:

Imidacloprid 9.10%

Pyriproxyfen 0.46%

OTHER INGREDIENTS: 90.44%

[TOTAL] 100.00%

KEEP OUT OF REACH OF CHILDREN WARNING

[See [Back][or][Side][Label[s]][Panel[s]] for Additional Precautionary Statements]

NET CONTENT: X fl oz [Y – X fl oz applicators]

[0.014 fl oz (0.4 mL) [tubes][vials][applicators][pipettes]]

[0.034 fl oz (1.0 mL) [tubes][vials][applicators][pipettes]]

[0.085 fl oz (2.5 mL) [tubes][vials][applicators][pipettes]]

[0.135 fl oz (4.0 mL) [tubes][vials][applicators][pipettes]]

[ABNs]

[SENTRY® Vet for Dogs Imidacloprid + Pyriproxyfen]

[SENTRY® Advanced for Dogs Imidacloprid + Pyriproxyfen]

[PetArmor® II for Dogs]

[PetArmor® Vet II for Dogs]

[SENTRY® VantaGuard II for Dogs]

[SENTRY® VantaGuard 2 for Dogs]

[SENTRY® VantaGuard 2 Flea Treatment for Dogs]

[SENTRY® VantaGuard 2 Flea Remedy for Dogs]

[SENTRY® Advanced FleaGuard II for Dogs]

[SENTRY® Advanced II for Dogs]

[SENTRY® FleaGuard II for Dogs]

[SENTRY® Advance Guard2 for Dogs]

[PetArmor® Advanced II for Dogs]

[PetArmor® Advanced 2 for Dogs]

[PetArmor® Advanced 2 Flea Treatment for Dogs]

[PetArmor® Advanced 2 Flea Remedy for Dogs]

[PetArmor® Advanced 2 Flea Guard for Dogs]

[PetArmor® FleaGuard II for Dogs]

[VantaGuard II for Dogs]

[Advanced FleaGuard II for Dogs]

[Advanced II for Dogs]

[FleaGuard II for Dogs]

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{Begin Optional Active Ingredient Reference Statements}

{Note to Reviewer – the following is an example statement:

Contains imidacloprid and pyriproxyfen, the active ingredients used in Advantage[®] II*

*[This product is not manufactured by Bayer Healthcare LLC, the makers of Advantage[®] II] [OR]
[Advantage[®] II is a registered trademark of Bayer Healthcare LLC]}

[{Brand Name} {This product} contains imidacloprid and pyriproxyfen, the active ingredients used in

[Advantage[®] II] [Advantage[®] II Small Dog] [Advantage[®] II Medium Dog] [Advantage[®] II Large Dog] [Advantage[®] II Extra Large Dog]]*

{Note to reviewer: Text for footnote statement one}

[*{Brand Name} {This product} is not manufactured or distributed by Bayer Healthcare LLC, the makers of

[Advantage[®] II] [Advantage[®] II Small Dog] [Advantage[®] II Medium Dog] [Advantage[®] II Large Dog] [Advantage[®] II Extra Large Dog]]

{Note to reviewer: Text for footnote statement two}

**[Advantage[®] II] [Advantage[®] II Small Dog] [Advantage[®] II Medium Dog] [Advantage[®] II Large Dog] [Advantage[®] II Extra Large Dog]*

is a registered trademark of Bayer Healthcare LLC.]

[End Optional Active Ingredient Reference Statements]

[Flea Marketing Claims]

[Prevents further flea infestation for [[four][4] weeks][1 month] with one treatment]

[Prevents further flea infestation for [[four][4] weeks][1 month] with one application]

[One treatment prevents further flea infestation for a month]

[For the prevention and treatment of Flea Infestations]

[[Brand Name] Prevents further flea infestation for [[four][4] weeks][1 month]]

[Kills fleas within 12 hours on dogs [and prevents further infestations for [up to] [[4][four] weeks][[1][one][a] month]]]

[Kills fleas within 12 hours [of application][on dogs]]

[Kills reinfesting fleas within 2 hours [and protects against further infestation]]

[Kills fleas before eggs can be laid]

[[Brand Name][{This product} kills fleas and may reduce the incidence of a hypersensitivity skin disorder called flea allergy dermatitis (FAD), which may be caused by the feeding activity of fleas on dogs.]

[Apply monthly [for effective flea control]]

[Apply monthly [to control and prevent fleas]]

[Monthly treatments are required for optimal control and prevention of fleas]

[Kills fleas]

[Kills fleas even if your dog gets wet]

[Kills fleas within 12 hours, continues to kill for 4 weeks]

[Kills fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation]

[Kills fleas, which may be a source of flea allergy dermatitis within 12 hours]

[Controls existing flea infestation by killing adult fleas]

[Active against fleas]

[Kills multi-stages of fleas]

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[Kills fleas on dogs]

[Kills fleas on dogs and puppies 7 weeks or older and 3-10 or 11-20 or 21-55 or over 55 pounds

[lbs]] {weight range depends upon appropriate ml/fl oz package size}

[(Begins/Starts) working through contact]

[[Brand Name] Offers protection against fleas]

[Once per month topical flea treatment for dogs]

[Monthly topical flea treatment for dogs]

[Once-a-month topical treatment for fleas on dogs]

[[Brand Name][This product] is for the treatment and prevention of fleas on dogs]

[Flea control for puppies and dogs over 7 weeks [old][of age] and 3-10 or 11-20 or 21-55 or over 55

lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[Flea control for puppies and dog 7 weeks [of age] or older] and 3-10 or 11-20 or 21-55 or over 55

lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[[Once per month][Monthly] topical flea treatment for dogs over 7 weeks [old][of age] and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[[Once per month][Monthly] topical flea treatment for dogs 7 weeks [of age] or older and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[Once-a-month topical treatment for fleas on dogs 7 weeks [of age] or older and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[[Brand Name][This product] is for the treatment and prevention of fleas on dogs over 7 weeks [old][of age] and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[[Brand Name][This product] is for the treatment and prevention of fleas on dogs 7 weeks [of age] or older and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[Prevents and treats flea[s] [infestations]]

[Controls existing infestations by killing adult fleas]

[[Use of Brand Name][Use of this product] kills fleas and may reduce incidence of flea bite hypersensitivity] [and][or] [flea allergy dermatitis] [FAD]]

[[Use of Brand Name][Use of this product] kills fleas and may reduce incidence of [flea bite hypersensitivity] [and][or] flea allergy dermatitis [FAD]]

[Monthly treatment [with Brand Name][with this product] kills fleas and may reduce incidence of [flea bite hypersensitivity] [and][or] flea allergy dermatitis [FAD]]

[Monthly treatment [with Brand Name][with this product] kills fleas and may reduce incidence of flea bite hypersensitivity [and][or] [flea allergy dermatitis] [FAD]]

[May be used year-round for control of fleas]

[Controls fleas, which can serve as an intermediate tapeworm host]

[Controls against [irritating] flea bites]

[Prevents further flea infestations on dogs for 30 days [1 month]]

[Prevents flea re-infestations for 30 days [1 month]]

[IGR Marketing Claims]

[Prevents flea eggs from hatching]

[Prevents flea eggs from developing into [biting] adult fleas]

[Prevents the development of flea eggs into [biting] adult fleas]

[Controls existing flea eggs]

[Kills flea eggs]

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[[Brand Name][This product] contains Pyriproxyfen [PPF] [an insect growth regulator (IGR)] to kill flea eggs [and protect against reinfestation]]

[Brand Name] contains [an][the] [insect growth regulator] [IGR] [, Pyriproxyfen] [, in addition to imidacloprid]

[Targets multi-stages of flea lifecycle]

[Controls multi-stages of flea lifecycle]

[Kills multiple flea life stages]

[[Brand Name][This product] is a flea ovicide, larvicide, and adulticide]

[Provides multi-stage flea control]

[Kills [flea eggs and] flea larvae]

[Breaks the flea life cycle]

[Kills flea eggs and flea larvae for up to four [4] weeks][1 month]]

[Prevents multi-stages of the flea life cycle from developing]

[[Brand Name][This product] inhibits the immature flea life stages (except pupae) from developing and preventing them from becoming [biting] adult[s] [fleas]]

[Monthly treatment controls existing flea eggs and fleas and prevents future infestations]

[Controls existing flea eggs and fleas and prevents future infestations for 30 days [1 month]]

[COMBO Marketing Claims]

[3-way flea protection kills adults, larvae and eggs]

[Kills flea eggs, larvae, and [adult] fleas]

[Kills [adult] fleas, flea eggs, and flea larvae]

[Kills [adult] fleas, flea eggs and flea larvae for up to four [4] weeks][1 month]]

[Kills [adult] fleas, larvae, and eggs [, providing three-way protection]]

[All Other Marketing Claims]

[Apply to [dogs and] puppies over 7 weeks old and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]]
{weight range depends upon appropriate ml/fl oz package size}

[Apply to [dogs and] puppies 7 weeks or older and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]]
{weight range depends upon appropriate ml/fl oz package size}

[From the makers of PetArmor®]

[[Sergeant's] Caring For Your Pets Since 1868]

[Formulated for Dogs and Puppies Over 7 Weeks [Old][of Age] and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[Formulated for Dogs and Puppies 7 Weeks [of Age] or Older and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[Dogs and Puppies over 7 weeks [old][of age] [or] 7 weeks [of age] or older and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[Can be used on puppies over 7 weeks [old][of age] [or] 7 weeks [of age] or older and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[The Only Flea Protection You Need For Your Dog[s] When Applied Monthly!]

[Convenient]

[Easy application]

[Easy to apply product]

[Easy to Use [Application]]

[Convenient, easy to apply topical solution]

[One Step Hassle Free Protection!]

[Waterproof]

[Remains effective, even after [bathing,][shampooing,] water immersion, or exposure to [sunlight]

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Information in [] is optional.

Information in { } is note to reviewer.

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[and][or] rain]

[Fragrance[-]free]

[Remains effective even after the dog swims]

[Once a month treatment]

[Apply once every [4 weeks] [month] [30 days]!]

[4 Week Dose!] [1 Month Dose!] [30 Day Dose!]

[For year-round protection, apply [Brand Name][this product] monthly]

[One tube [vial][pipette]] [1 Month Supply]

[Two tube [vials][pipettes]] [2 Month Supply]

[Three tube [vials][pipettes]] [3 Month Supply]

[Four tube [vials][pipettes]] [4 Month Supply]

[Five tube [vials][pipettes]] [5 Month Supply]

[Six tube [vials][pipettes]] [6 Month Supply]

[9 tube [vials][pipettes]] [9 Month Supply]

[12 tube [vials][pipettes]] [12 Month Supply]

[24 tube [vials][pipettes]] [24 Month Supply]

[Direct to skin [tube][vial][applicator][pipette]]

[Easy to Use] [tube][vial][applicator][pipette]

[No-mess [open] [tube][vial][applicator][pipette]]

[Clip-tip design [tube][vial][applicator][pipette][!]]

[Consumer Value Marketing Claims]

[Coupon Inside]

[Save Now!]

[Value Size]

[Club Size]

[Bonus Size]

[Club Pack]

[Great Value]

[Better Value]

[Bonus Pack]

[Bonus Buy]

[[1][2][4][6][7][8][9][X] pack]

[Twin Pack]

[Try Now, Save Later!]

[Z%Free]

[(x) + (x) bonus pack!]

[Buy more and save!]

[Buy X Get Y Free]

[Buy 3 get 1 free]

[(x)% (More) (Free)!]

[33% more free]

[(x) Dose(s) Free!]

[(x) Day(s) (Free)!]

[(x) Month(s) Free!]

[(x) Day(s) of treatment- Free!]

[(x) Tube(s) Free!]

[(x) Applicator(s) Free!]

[(x) Application(s) Free!]

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[33% More Free]

[[New!]] {only for use for 6 months from date of registration}

{END – FRONT PANEL}

BACK PANEL/SIDE PANEL

Dogs Squeeze On Imidacloprid + Pyriproxyfen

[The active ingredients in [Brand name][this product] are imidacloprid and pyriproxyfen. This product is formulated to control fleas [, flea eggs, and flea larvae] on dogs.] [[Brand Name][This product] kills fleas within 12 hours and prevents further flea infestations for [up to] [[4][four]weeks][[1][one] month][30 days].]

READ ENTIRE LABEL BEFORE EACH USE.
USE ONLY ON DOGS AND PUPPIES 7 WEEKS OF AGE OR OLDER.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. WARNING. Causes substantial but temporary eye injury. Harmful if swallowed. Do not get in eyes or on clothing. Wash hands thoroughly with soap and warm water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS. For external use on dogs only. Individual sensitivities, while rare, may occur after using ANY pesticide product for dogs. Do not treat your dog with more than one pesticide product at a time. Over dosing your dog can result in serious illness and even death. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing dogs.

FIRST AID	
If Swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If In Eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If on Skin or Clothing	<ul style="list-style-type: none">• Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-781-4738 for emergency medical treatment information.	
NOTE TO PHYSICIAN	
Treat the patient symptomatically.	

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DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.

Restrictions:

- **DO NOT ALLOW CHILDREN TO APPLY PRODUCT.**
- Do not use on animals other than dogs.
- Do not allow your dog to ingest this product.
- Do not reapply for [[four] [4] weeks][30 days]
- Do not get in dog's eyes.
- Use entire contents of tube [vial][applicator][pipette] on each dog. Do not split one tube [vial][applicator][pipette]s between dogs. Do not use multiple tube [vial][applicator][pipette]s on one dog.
- Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog.
- Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied.
- Do not have contact or allow children to have contact with the treated area until completely dry.

{Side Effects box to be located on label above the cat prohibition icon/text all on the lower right hand side of the back panel}

Side Effects: Monitor your dog after application. [Some dogs may experience temporary startle effects when any product is applied.] Dogs may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe your dog with a mild soap and rinse with large amounts of water. If these or other side effects occur, consult your veterinarian or call 1-800-781-4738. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your dog and continue to monitor your dog for the next 24 hours.

[1.5 cm x 1.5 cm on final or as indicated]

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. Contact your veterinarian if applied to a cat or ingested by a cat.



{OUTER PACKAGING}

How to Open:

1. Remove product tube[s] [vial[s]][applicator[s]][pipette[s]] from the package.
2. Separate one tube [vial][applicator][pipette] from the others. Hold the tube [vial][applicator][pipette] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply:

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1. Invert tube [vial][applicator][pipette] over dog and use open end to part dog's hair.
2. Squeeze tube [vial][applicator][pipette] firmly to apply all of the solution to the dog's skin as a spot to the dog's back between the shoulder blades. [or] [from the back of the neck to a point midway between the neck and tail.]

{For cartons containing 0.4 mL (0.014 fl oz) applicator tubes}

Only For Dogs Weighing 3 [-][to] 10 lbs. Do not apply to dogs weighing less than 3 lbs.

[including small dogs and puppies, only 7 weeks or older] Apply one

[tube][vial][applicator][pipette] 0.4 mL (0.014 fl oz) directly to skin [either] [as a spot [on] [to] the dog's back between the shoulder blades] [or] [as a [stripe] [line] starting from the back of the neck to a point midway between the neck and tail].

{For cartons containing 1.0 mL (0.034 fl oz) applicator tube}

Only For Dogs Weighing 11 [-][to] 20 lbs. Do not apply to dogs weighing less than 11 lbs.

Apply one tube[vial][applicator][pipette] 1.0 mL (0.034 fl oz) directly to skin [either] as a spot [on] [to] the dog's back between the shoulder blades [or] [as a [stripe] [line] starting from the back of the neck to a point midway between the neck and tail].

{For cartons containing 2.5 mL (0.085 fl oz) applicator tube}

Only For Dogs Weighing 21 [-][to] 55 lbs. Do not apply to dogs weighing less than 21 lbs.

Apply one tube[vial][applicator][pipette] 2.5 mL (0.085 fl oz) directly to skin [either] as a spot [on] [to] the dog's back between the shoulder blades [or] [as a [stripe] [line] starting from the back of the neck to a point midway between the neck and tail].

{For cartons containing 4.0 mL (0.135 fl oz) applicator tube}

Only For Dogs Weighing 55 lbs. or greater. Do not apply to dogs weighing less than 55 lbs. Do not use two [tube][vial][applicator][pipette]s on dogs greater than 55 lbs. Apply one

tube[vial][applicator][pipette] 4.0 mL (0.135 fl oz) directly to skin [either] as a spot [on] [to] the dog's back between the shoulder blades [or] [as a [stripe][line] starting from the back of the neck to a point midway between the neck and tail].

FREQUENCY OF APPLICATION

[Use [Brand Name {or} this product] monthly for control of flea[s] [infestations].] [[Studies show that] [Brand Name {or} This product] kills fleas within 12 hours of application and [lasts {or} protects [for [up to] [[four][4] weeks][30 days][one month].]

[[Brand Name {or} This product] kills reinfesting fleas within [2][two] hours][two hours] and prevents further infestations of fleas [for [up to] [[four][4] weeks][30 days][one month]].]

[[Brand Name {or} This product] [targets multiple flea life stages] [and] [kills flea eggs and larvae before they develop into biting adults].]

[[Brand Name {or} This product] breaks the flea life cycle by killing flea eggs, flea larvae, and adult fleas.]

[If your dog is at high risk for flea reinfestation [, or in a highly infested environment], apply monthly.] [Apply monthly for flea control.]

[[Brand Name {or} This product] is waterproof and remains effective, even after bathing, swimming, or exposure to sunlight [and][or] [rain].] [Allow treated area to dry thoroughly.]

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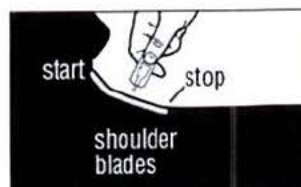
Information in [] is optional.

Information in { } is note to reviewer.

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[How to Apply - May contain graphics illustrating product use, e.g., dog with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling. Refer to following optional graphics.]



STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not remove [tube][vial][applicator][pipette] from the pack until ready to use. Store only in original container in a cool [(below 77°F/[](25°C))], dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

CONTAINER DISPOSAL: **If empty:** Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[WARRANTY

Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. The directions for use of this product are believed to adequate and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer. Sergeant's is committed to providing high quality products. To the extent consistent with applicable law, Sergeant's makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Sergeant's, the manufacturer, or the Seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[If you have questions or comments about this product, please write: [Sergeant's][SENTRY]
[PetArmor®] Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

[Satisfaction Guaranteed][If you are not satisfied, we will make it right with a replacement or refund.]

In Case of Emergency, call: 1-800-781-4738
Non-Emergency, call: 1-800-224-PETS (7387)

[Coupon(s) inside or on outside of box]
[Made in USA With Global Materials]

[Distributed by:] [Manufactured by:]
Sergeant's Pet Care Products, Inc.
Omaha, NE 68138-3710

EPA Reg. No. 2517-RTA
EPA Est. No. XXXXX-XX-XX
[BAR CODE AREA]

{END - BACK/SIDE PANEL}

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{START – ADDITIONAL OPTIONAL PACKAGE COPY OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE OR INSERT}

[Clip. Part. Squeeze.]

[Easier-than-ever applicator lets you *clip* the tip, *part* the fur and *apply* directly to the skin – putting proven flea protection where it needs to be.]

[Application Instructions]

How to Open:

1. Remove product tube[s] [vial[s]][applicator[s]][pipette[s]] from the package.
2. Separate one tube [vial][applicator][pipette] from the others. Hold the tube [vial][applicator][pipette] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply:

1. Invert tube [vial][applicator][pipette] over dog and use open end to part dog's hair.
2. Squeeze tube [vial][applicator][pipette] firmly to apply all of the solution [on] [to] the dog's skin as a spot to the dog's back between the shoulder blades. [or] [from the back of the neck to a point midway between the neck and tail.]

Look at the Label [Easy] 6 Step [Easy] [Spot On] [Squeeze-On] [Topical] Checklist

- [1] Read the label completely and follow directions
- [2] Weigh your dog
- [3] Do NOT use dog products on cats
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate animals after [treatment {or} application] to avoid chance of ingestion
- [6] Do NOT split [tube][vial][applicator][pipette] between dogs][and use the ENTIRE [tube][vial][applicator][pipette] contents]

[Brand Name][This product]

[Monthly reminder card]

[1][2][3][4][5][6][12][24][Month [Treatment] [Application] Tracker][Carecard]

[For year-round protection, apply [Brand Name][this product] monthly.]

[Dog's Name (Empty blank for owner to fill in name)]

[Dog's Weight (Empty blank for owner to fill in name)]

[First][1st][Second][2nd][Third][3rd][Fourth][4th][Fifth][5th][Sixth][6th][Seventh][7th][Eighth]

[8th][Ninth][9th][Tenth][10th][Eleventh][11th][Twelfth][12th]

[Dose] [Treatment] [Application](Empty blank for owner to fill in date)(Date: MM/DD/YY)

[Application Date][Date of Application]

[Calendar stickers with Brand Name]

[Place stickers on your calendar as a reminder to reapply [Brand Name][this product] [in 30 days.]

[Monthly Application Reminder Magnet (image of reminder magnet)]

[Place sticker on your calendar [or refrigerator] to remind yourself to apply [Brand Name][this product] to your dog]

[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days the reminder light will blink, reminding you to reapply [Brand Name][this product]. Press the button

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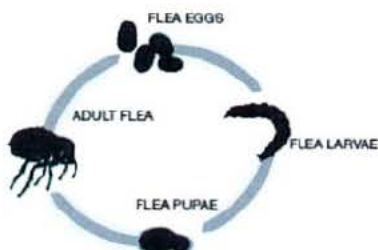
once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

[Each optional graphic below may or may not appear anywhere on the finished label]

	Adult Flea	
	Fleas	
	Flea eggs	
	Flea Larvae	



MADE IN THE
USA
WITH GLOBAL MATERIALS



[Flea life cycle diagram] [Flea Life Cycle]



{non-mandatory optional graphics that may be used in addition to the EPA mandatory icon requirements that currently appear on the label.}

*Refund or replacement of product {text footnote to satisfaction guaranteed graphic}

{END – ADDITIONAL OPTIONAL PACKAGE COPY OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE OR INSERT}

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Information in { } is note to reviewer.

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TUBE/VIAL LABEL

Dogs Squeeze On Imidacloprid + Pyriproxyfen

{Front Label}

{Back Label}

Brand Name {for dogs}

3-10[11-20][21-55][>55] lbs. ≥7 wks

Imidacloprid 9.10%, Pyriproxyfen 0.46%

0.014 fl oz (**or**) 0.034 fl oz (**or**) 0.085 fl oz

(**or**) 0.135 fl oz {label code}



KEEP OUT OF REACH OF CHILDREN

WARNING Read directions and precautions
on package. Use scissors to open.

EPA REG. No. 2517-RTA {label code}

{EPA REG No may be on either the front or back label}

{Label code refers to Sergeant's product code number assignment to each product}

{END – TUBE/VIAL LABEL}

Lewis, Marianne

From: Prince Bamaze <Prince.Bamaze@perrigo.com>
Sent: Friday, March 24, 2017 5:13 PM
To: Lewis, Marianne
Cc: Davis, Kable; Kelly Hoskins; Prince Bamaze
Subject: RE: 2517-175 6a2 review - Response requested [WARNING: DKIM validation failed]
Attachments: 2517-175 V17.1 AMND ML HL 20Mar17.pdf; 2517-175 V17.1 AMND ML Clean 20Mar17.pdf; 2517-176 V17.1 AMND ML HL 20Mar17.pdf; 2517-176 V17.1 AMND ML Clean 20Mar17.pdf

Hi Marianne,

Attached are pdf copies of the labels. Please let me know if you need anything else.

Thank you,

Prince Bamaze | Regulatory Affairs Associate
Perrigo Animal Health
T: (402) 938-7065
F: (402) 938-7165
E: prince.bamaze@perrigo.com | perrigoanimalhealth.com

From: Kelly Hoskins
Sent: Friday, March 24, 2017 1:55 PM
To: Lewis, Marianne
Cc: Prince Bamaze
Subject: RE: 2517-175 6a2 review - Response requested [WARNING: DKIM validation failed]

Yes we can.

Kelly R Hoskins
Manager of Regulatory Affairs

From: Lewis, Marianne <Lewis.Marianne@epa.gov>
Sent: Friday, March 24, 2017 1:53:01 PM
To: Kelly Hoskins
Subject: RE: 2517-175 6a2 review - Response requested [WARNING: DKIM validation failed]

Hey Kelly,

Would it be possible to get the individual label pdf's for 2517-175 & -176? We stamp/flatten these for the record and when it's attached to other documents we can't do that.

Thanks much

Marianne

From: Kelly Hoskins [mailto:Kelly.Hoskins@perrigo.com]
Sent: Friday, March 24, 2017 1:57 PM
To: Lewis, Marianne <Lewis.Marianne@epa.gov>
Cc: Prince Bamaze <Prince.Bamaze@perrigo.com>; Davis, Kable <Davis.Kable@epa.gov>
Subject: RE: 2517-175 6a2 review - Response requested [WARNING: DKIM validation failed]

Marianne,
Yes we did receive and have already responded per the letters, sorry for the miscommunication.

Kelly Hoskins | Manager of Regulatory Affairs
Sergeant's Pet Care Products, Inc. dba Perrigo Animal Health
10077 South 134th Street
Omaha, NE 68138-3710
T: (402) 938-7079
E: kelly.hoskins@perrigo.com | perrigoanimalhealth.com

Quality Affordable Healthcare Products® for Pets!



From: Lewis, Marianne [mailto:Lewis.Marianne@epa.gov]
Sent: Friday, March 24, 2017 9:50 AM
To: Kelly Hoskins <Kelly.Hoskins@perrigo.com>
Subject: FW: 2517-175 6a2 review - Response requested

Hi Kelly,

Haven't heard from you regarding the acute tox review for 2517-175 – just wanted to make sure you actually received the 3/10/17 email & attachments so am resending them. Please send me a revised label next week to review.

Thanks,

Marianne

From: Lewis, Marianne
Sent: Friday, March 10, 2017 3:22 PM
To: 'kelly.hoskins@perrigo.com' <kelly.hoskins@perrigo.com>
Subject: FW: 2517-175 6a2 response

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 10, 2017

Kelly R. Hoskins
Director of Regulatory Affairs
Sergeant's Pet Care Products, Inc.
dba Perrigo Animal Health
10077 South 134th Street
Omaha, NE 68138-3710

Subject: Agency Initiated Action – review of 6(a)2 data submitted
Product Name: Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs
EPA Registration Number: 2517-176

Dear Mr. Hoskins:

Upon review of the 6(a)2 data submitted by Sergeant's, MRID 50167801 – 870.2400 Primary Eye Irritation in Rabbits, the following changes need to be made to the EPA Reg. No. 2517-176 product label:

- 1) The signal word is to be changed from 'CAUTION' to 'WARNING', everywhere it appears on the label, based on the result of the primary eye irritation study submitted.
- 2) On page 7 of the label, revise the "Hazards to Humans" statement to read as follows:

"Warning. Causes substantial but temporary eye injury. Harmful if swallowed. Do not get in eyes or on clothing. Wash hands thoroughly with soap and warm water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet."
- 3) On page 7 of the label, under "Restrictions" add the following bullet:
 - Do not get in dog's eyes.

Please submit a revised label within 10 days of the date of this letter. If you have any questions, please contact Marianne Lewis by phone at (703) 308-8043, or via email at lewis.marinne@epa.gov.

Sincerely,

Elyssa Arnold, Acting Product Manager 01
Invertebrate & Vertebrate Branch 3
Registration Division (7505P)
Office of Pesticide Program

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

Subject: EPA Reg. No.: 2517-176/Sergeant's Imidacloprid (9.1%) + Pyriproxyfen (0.9%)
for Dogs
DP Barcode: 438511
PC Code: 129099 (imidacloprid), 129032 (pyriproxyfen)

From: Marianne Lewis, Biologist
Invertebrate and Vertebrate Branch 3
Registration Division (7508P)

To: Elyssa Arnold, Acting PM 01
Invertebrate and Vertebrate Branch 3
Registration Division (7508P)

Applicant: Sergeant's Pet Care Products, Inc.
10077 South 134th Street
Omaha, NE 68138-3710

[Handwritten signature: Marianne Lewis]
[Handwritten initials: J.R.]
[Handwritten date: 3/6/17]

FORMULATION FROM EPA Reg. No. 2517-176 LABEL:

	<u>% by wt.</u>
<u>Active Ingredient(s):</u>	
Imidacloprid:	9.1%
Pyriproxyfen:	0.9%
<u>Inert Ingredient(s):</u>	90.0%
Total	100.0%

BACKGROUND: The registrant is citing, under a 6(a)2 data requirement, a new primary eye irritation study conducted on to their product, EPA Reg. No. 2517-175 which is substantially similar to 2517-176 (the subject product). The MRID is 501678-01 (81-4). The study was conducted by Product Safety Labs. The test material used the study was 2517-175 which was initially registered citing acute toxicity studies conducted on a Bayer Animal Health product. However, to support international registration the registrant had to conduct the full six pack on 2517-175. The registrant states in their cover letter that the acute toxicity studies for acute oral, acute dermal, dermal irritation, and dermal sensitization were similar in severity and outcome as those originally cited. The new primary eye irritation study resulted in a different toxicity category than what was originally cited, therefore, the primary eye irritation study has now been reviewed by the Agency as 6(a)2 data. The Agency has not seen the rest of the new acute tox six pack so the tox categories listed below are from what was previously cited.

RECOMMENDATIONS:

- The primary eye irritation study (81-4) cited is acceptable to support EPA Reg. No. 2517-176. Please note that the Signal word has now changed to “Warning”

The acute toxicity profile for EPA Reg. No. 2517-176 is currently:

Acute Oral	III	cited
Acute Dermal	IV	cited
Acute Inhalation	IV	waived
Primary Eye	II	Cited
Primary Dermal	IV	cited
Skin Sensitization	non sensitizer	cited

NOTE: The acute toxicity requirements have been satisfied for the subject product.

LABELING:

ID #: 002517-176 SERGEANT'S IMIDACLOPRID (9.1%) +
PYRIPROXYFEN (0.9%) FOR DOGS

SIGNAL WORD: **WARNING**

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

Causes substantial but temporary eye injury. Harmful if swallowed. Do not get in eyes or on clothing. Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

FIRST AID:

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing the eye. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

Memorandum

2517 - 175
-176

6(a)2
Alceta

Date: 2 / 22 / 17

To: PH 01, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☐ partially accepted submission
☐ rejected submission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

February 22, 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

SERGEANT'S PET CARE PRODUCTS, INC.
PO.BOX : 540399
OMAHA, NE 68154-0399

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 24-JAN-17. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

S: 998027

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: Amendment

Fee For Service: ☐ Yes ☒ No

Billable: ☒ Yes ☐ No

Company: 2517 SERGEANT'S PET CARE PRODUCTS, INC.

V

Print Letter

Enter More Information

Tracking

Risk Manager: Registration Division, Risk Management Team 1

Product #: 2517-176 Product Name: Sergeant's Imidacloprid + Pyriproxyfen Squeez

Override#:

Me Too

Me Too Product

Section3:

Name:

Application Date: 24-Jan-2017



OPP Rec'd Date: 24-Jan-2017



Front End Date: 24-Jan-2017



Risk Manager Send Date:



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Toxicological study-6A2

Receipt Content

De

Study

View/Edit

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:



ISB

50167800

Sergeant's Pet Care Products, Inc.

10077 South 134th Street • Omaha, NE 68138- 3710 • Telephone 402.938.7000 • Fax 402.938.7091 • www.sergeants.com

January 24, 2017

Document Processing Desk – 6(a)(2)
Office of Pesticide Programs – (7504P)
U. S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

**SUBJECT: 40 CFR §159.165 (a)(2) Toxicological Study
(EPA Reg. No. 2517-175 and 2517-176)**

Dear Sir/Madam:

Enclosed please find three copies of Sergeant's Pet Care Products, Inc. (Sergeant's), Report Number 43661, *Primary Acute Eye Irritation Study in Rabbits*. This study is being submitted to you in accordance with FIFRA Section 6(a)(2) as a possible adverse effect.

Sergeant's holds end-use product registrations for the following products:

- Sergeant's Imidacloprid (9.1%) + Pyriproxyfen (0.9%) for Cats (2517-175)
- Sergeant's Imidacloprid (9.1%) + Pyriproxyfen (0.9%) for Dogs (2517-176)

Initially, Bayer Animal Health (BAH) acute toxicology data were cited to support Sergeant's end-use products for dogs and cats. Sergeant's conducted new acute toxicity studies on their specific product formulation to support international registration efforts. While the results of Sergeant's acute toxicity studies for acute oral, acute dermal, dermal irritation, and dermal sensitization were similar in severity and outcome to those reported in the BAH sponsored acute toxicity tests, the primary acute eye irritation study in the rabbit presents some differences that warrant reporting under FIFRA Section 6(a)(2). The delay of this submission was due to the realization that this international data requirement would also be subject to FIFRA requirements.

Compared to the BAH sponsored *Primary Acute Eye Irritation Study with Imidacloprid (9.1%) + Pyriproxyfen (0.9%) Spot-on in Rats* (MRID 45096907) that reported eye effects clearing completely by day 7, with a mean irritation score of zero, the Sergeant's sponsored Primary Acute Eye Irritation Study (MRID TBD) reported effects that persisted until study termination on day 14, with a mean eye irritation score of 14. While the reported eye effects were similar, the durations of persistence were not.

Document Processing Desk – 6(a)(2)
January 24, 2017
Page Two

Based on the increased persistence of the eye effects noted in the new Sergeant's sponsored primary eye irritation study, these changes are considered reportable in accordance with 40 CFR §159.165(a)(2).

Please call me at (402) 938-7079 or via email at kelly.hoskins@perrigo.com if I can provide you with further information or if you have any questions.

Sincerely,



Kelly R. Hoskins
Director of Regulatory Affairs
Sergeant's Pet Care Products, Inc. dba Perrigo Animal Health

cc: EPA Product Manager

Enclosure (Report No. 43661 (3 copies))

Transmittal

Submitter:

Sergeant's Pet Care Products, Inc.

10077 South 134th Street

Omaha, NE 68138

MRID:

50167801

STUDY:

Imidacloprid + Pyriproxyfen Spot On for Dogs and Cats: Primary Eye Irritation in Rabbits

Kumar, Rita

From: Kumar, Rita
Sent: Tuesday, August 09, 2016 10:45 AM
To: Kelly Hoskins (Kelly.Hoskins@perrigo.com)
Subject: Pending notification for 2517-176
Attachments: 2517-176 D520059 ABN 8-8-2016.pdf

Please see attached. This action is now complete.

Regards,
Rita



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 8, 2016

Kelly R. Hoskins
Manager of regulatory Affairs
Sergeant's Pet Care products, Inc.
10077 South 134th Street
Omaha, NE 68138-3710

Subject: Notification per PRN 98-10 – Alternate brand name
Product Name: Sergeant's Imidacloprid + Pyriproxifen Spot-On for Dogs
EPA Registration Number: 2517-176
Application Date: June 16, 2016
Decision Number: 520059

Dear Ms. Hoskins:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The alternate brand name Sentry Advance Guard2 for Dogs has been added to the product record.

If you have any questions, you may contact Rita Kumar at (703) 308-8291 or via email at kumar.rita@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Rita Kumar" followed by a stylized flourish or initial.

Venus Eagle, Product Manager 01
Insecticide-Rodenticide Branch 3
Registration Division (7505P)
Office of Pesticide Programs

June 16, 2016

Kable (Bo) Davis, PM 3
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk (NOTIF)
Room S-4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202-4501

Subject: **Notification for new Alternate Brand Names per PR Notice 98-10.**

Dear Mr. Davis,

Sergeant's Pet Care Products, Inc. (EPA Company Number 2517) is hereby submitting applications for notification, to add alternate brand names to the EPA Registration Numbers listed below. In support of this action, please find enclosed an Application (EPA Form 8570-1) for each EPA Registration Number listed:

Sergeant's Imidacloprid + Pyriproxyfen Spot-On for Cats,
EPA Registration Number: 2517-175

Sentry Advance Guard2 for Cats

Sergeant's Imidacloprid + Pyriproxyfen Squeeze-On for Dogs,
EPA Registration Number: 2517-176

Sentry Advance Guard2 for Dogs

This Notification is consistent with provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make a false statement to the EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Should you have any questions regarding this submission, please contact me at 402-938-7079 or by email at kelly.hoskins@Perrigo.com.

Sincerely,



Kelly R. Hoskins

Manager of Regulatory Affairs,
Sergeant's Pet Care Products, Inc., d.b.a. Perrigo Animal Health

Enclosures



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

2517-176

Date of Issuance:

3/10/16

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
Expires: 3/10/2018

Name of Pesticide Product:

Sergeant's Imidacloprid +
Pyriproxifen Squeeze On for Dogs

Name and Address of Registrant (include ZIP Code):

Kelly R. Hoskins
Sergeant's Pet care Products, Inc.
10077 South 134th Street
Omaha, NE 68138-3710

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Venus Eagle, Product Manager 01

Invertebrate-Vertebrate Branch 3, Registration Division (7505P)

Date:

3/10/16

2. This registration is time-limited and expires 3/10/2018.
3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning within 3 months of the date the product is first released for shipment, on the first day of the quarter (i.e., January 1, April 1, July 1, or October 1). Please flag any Confidential Business Information as such. Submit enhanced incident reporting and quarterly sales information to the Product Manager's attention. The following is a list of information that must be included in the quarterly reports for each incident:
 - EPA Registration Number
 - Product name (brand name)
 - Lot #
 - Where purchased: internet, store, veterinarian
 - Active Ingredient(s)
 - Weight range for product
 - Date on which incident occurred (mm/dd/yyyy)
 - State in which the incident occurred (standard 2 letter abbreviation)
 - Registrant case #
 - Species: dog, cat, other (specify)
 - Breed: (as reported by pet owner)
 - Age: months or years
 - Sex: M, F, or neutered
 - Weight: pounds
 - Primary Route of Exposure: dermal, oral, other animal, inhalation, other
 - Body System: neurological, dermatological, GI, respiratory, ocular, other
 - Major signs noted with separate column for each sign, using standard terminology
 - Time to Onset: (hours, days)
 - Treated by veterinarian: yes or no
 - First time product used: yes or no
 - Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
 - Any known precondition
 - EPA Severity Code: death, major, moderate, minor
 - Outcome: died, recovered, still treated, unknown
4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:
 - *All incidents should be reported including all minor dermal and ocular irritation reports.*
 - Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.

- A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for cats and table for dogs showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label, as applicable.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range, as applicable.
- Table showing number of incidents for each dog breed, where provided.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

5. You are required to comply with the data requirements described in the DCI and EDSP Orders identified below:
 - a. Imidacloprid GDCI-129099-951
 - b. Pyriproxyfen GDCI-129032-1299
 - c. Imidacloprid EDSP-129099
 - d. Pyriproxyfen EDSP-129032

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI or EDSP Orders listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:
http://www.epa.gov/oppsrrd1/contacts_prd.htm

6. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 2517-176."
7. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded

and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 2/29/2016

If you have any questions, please contact Rita Kumar by phone at (703) 308-8291 or via email at kumar.rita@epa.gov.

Enclosure

Sergeant's® Master Label

10 Mar 2016

Version 16.1

EPA Reg. No. 2517-RTA

Information in [] is optional.

Information in { } is note to reviewer.

Page 1 of 13

FRONT PANEL

Dogs Squeeze On Imidacloprid + Pyriproxyfen

[Optional text appears in brackets/parenthesis – the final label may include some or all of the optional text on front, back or side label panels]

Sergeant's® Imidacloprid + Pyriproxyfen Squeeze On for Dogs

{Market Label-the word Dog will be at least 40-75% in height of the largest letter in the primary brand name.}

{Market Label-a large clear picture of a dog in the respective weight range will be on the front panel of the label for the product as packaged.}

{One of the following statements will appear on appropriate weight band market label on front panel as required per Agency's pet spot-on mitigation measures:}

For use ONLY on dogs [[&][and] puppies] [weighing] 3 [-][to] 10 lbs. and over 7 weeks [old][of age] {0.4 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] 3 [-][to] 10 lbs. and 7 weeks [of age] or older {0.4 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] 11 [-][to] 20 lbs. and over 7 weeks [old][of age] {1.0 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] 11 [-][to] 20 lbs. and 7 weeks [of age] or older {1.0 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] 21 [-][to] 55 lbs. and over 7 weeks [old][of age] {2.5 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] 21 [-][to] 55 lbs. and 7 weeks [of age] or older {2.5 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] [more than][over][>] 55 lbs. and over 7 weeks [old][of age] {4.0 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] [more than][over][>] 55 lbs. and 7 weeks [of age] or older {4.0 ml size package}

ONLY for dogs [[&][and] puppies]] over 7 weeks [old][of age]] and [weighing] 3 [-][to] 10 lbs. {0.4 ml size package}

ONLY for dogs [[&][and] puppies]] 7 weeks [of age] or older and [weighing] 3 [-][to] 10 lbs. {0.4 ml size package}

ONLY for dogs [[&][and] puppies]] over 7 weeks [old][of age]] and [weighing] 11 [-][to] 20 lbs. {1.0 ml size package}

ONLY for dogs [[&][and] puppies]] 7 weeks [of age] or older and [weighing] 11 [-][to] 20 lbs. {1.0 ml size package}

ONLY for dogs [[&][and] puppies]] over 7 weeks [old][of age]] and [weighing] 21 [-][to] 55 lbs. {2.5 ml size package}

ONLY for dogs [[&][and] puppies]] 7 weeks [of age] or older and [weighing] 21 [-][to] 55 lbs. {2.5 ml size package}

ONLY for dogs [[&][and] puppies]] over 7 weeks [old][of age]] and [weighing] [more than] [over][>] 55 lbs. {4.0 ml size package}

ONLY for dogs [[&][and] puppies]] 7 weeks [of age] or older and [weighing] [more than] [over][>] 55 lbs. {4.0 ml size package}

ACCEPTED

Mar 10, 2016

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 2517-176

1.5cm x 1.5cm on final



Sergeant's® Master Label

10 Mar 2016

Version 16.1

EPA Reg. No. 2517-RTA

Information in [] is optional.

Information in { } is note to reviewer.

Page 2 of 13

{following text will be in addition to the above required language}

Small Dogs {only for use on label for 3-10 lbs and 7 weeks or older product}

Medium Dogs {only for use on label for 11-20 lbs and 7 weeks or older product}

Large Dogs {only for use on label for 21-55 lbs and 7 weeks or older product}

Extra Large Dogs {only for use on label for >55 lbs and 7 weeks or older product}

ACTIVE INGREDIENTS:

Imidacloprid 9.10%

Pyriproxyfen 0.46%

OTHER INGREDIENTS: 90.44%

[TOTAL] 100.00%]

KEEP OUT OF REACH OF CHILDREN CAUTION

[See [Back][or][Side][Label[s]][Panel[s]] for Additional Precautionary Statements]

NET CONTENT: X fl oz [Y – X fl oz applicators]

[0.014 fl oz (0.4 mL) [tubes][vials][applicators][pipettes]]

[0.034 fl oz (1.0 mL) [tubes][vials][applicators][pipettes]]

[0.085 fl oz (2.5 mL) [tubes][vials][applicators][pipettes]]

[0.135 fl oz (4.0 mL) [tubes][vials][applicators][pipettes]]

[ABNs]

[SENTRY® Vet for Dogs Imidacloprid + Pyriproxyfen]

[SENTRY® Advanced for Dogs Imidacloprid + Pyriproxyfen]

[PetArmor® II for Dogs]

[PetArmor® Vet II for Dogs]

[SENTRY® VantaGuard II for Dogs]

[SENTRY® VantaGuard 2 for Dogs]

[SENTRY® VantaGuard 2 Flea Treatment for Dogs]

[SENTRY® VantaGuard 2 Flea Remedy for Dogs]

[SENTRY® Advanced FleaGuard II for Dogs]

[SENTRY® Advanced II for Dogs]

[SENTRY® FleaGuard II for Dogs]

[PetArmor® Advanced II for Dogs]

[PetArmor® Advanced 2 for Dogs]

[PetArmor® Advanced 2 Flea Treatment for Dogs]

[PetArmor® Advanced 2 Flea Remedy for Dogs]

[PetArmor® Advanced 2 Flea Guard for Dogs]

[PetArmor® FleaGuard II for Dogs]

[VantaGuard II for Dogs]

[Advanced FleaGuard II for Dogs]

[Advanced II for Dogs]

[FleaGuard II for Dogs]

Sergeant's® Master Label

10 Mar 2016

Version 16.1

EPA Reg. No. 2517-RTA

Information in [] is optional.

Information in { } is note to reviewer.

Page 3 of 13

{Begin Optional Active Ingredient Reference Statements}

{Note to Reviewer – the following is an example statement:

Contains imidacloprid and pyriproxyfen, the active ingredients used in Advantage® II*

*[This product is not manufactured by Bayer Healthcare LLC, the makers of Advantage® II] [OR]
[Advantage® II is a registered trademark of Bayer Healthcare LLC]}

[[Brand Name] [This product] contains imidacloprid and pyriproxyfen, the active ingredients used in

[Advantage® II] [Advantage® II Small Dog] [Advantage® II Medium Dog] [Advantage® II Large Dog] [Advantage® II Extra Large Dog]]*

{Note to reviewer: Text for footnote statement one}

***[[Brand Name] [This product] is not manufactured or distributed by Bayer Healthcare LLC, the makers of**

[Advantage® II] [Advantage® II Small Dog] [Advantage® II Medium Dog] [Advantage® II Large Dog] [Advantage® II Extra Large Dog]

{Note to reviewer: Text for footnote statement two}

**[Advantage® II] [Advantage® II Small Dog] [Advantage® II Medium Dog] [Advantage® II Large Dog] [Advantage® II Extra Large Dog]*

is a registered trademark of Bayer Healthcare LLC.]

[End Optional Active Ingredient Reference Statements]

[Flea Marketing Claims]

[Prevents further flea infestation for [[four][4] weeks][1 month] with one treatment]

[Prevents further flea infestation for [[four][4] weeks][1 month] with one application]

[One treatment prevents further flea infestation for a month]

[For the prevention and treatment of Flea Infestations]

[[Brand Name] Prevents further flea infestation for [[four][4] weeks][1 month]]

[Kills fleas within 12 hours on dogs [and prevents further infestations for [up to] [[4][four] weeks][[1][one][a] month]]

[Kills fleas within 12 hours [of application][on dogs]]

[Kills reinfesting fleas within 2 hours [and protects against further infestation]]

[Kills fleas before eggs can be laid]

[[Brand Name][This product] kills fleas and may reduce the incidence of a hypersensitivity skin disorder called flea allergy dermatitis (FAD), which may be caused by the feeding activity of fleas on dogs.]

[Apply monthly [for effective flea control]]

[Apply monthly [to control and prevent fleas]]

[Monthly treatments are required for optimal control and prevention of fleas]

[Kills fleas]

[Kills fleas even if your dog gets wet]

[Kills fleas within 12 hours, continues to kill for 4 weeks]

[Kills fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation]

[Kills fleas, which may be a source of flea allergy dermatitis within 12 hours]

[Controls existing flea infestation by killing adult fleas]

[Active against fleas]

[Kills multi-stages of fleas]

Sergeant's® Master Label

10 Mar 2016

Version 16.1

EPA Reg. No. 2517-RTA

Information in [] is optional.

Information in { } is note to reviewer.

Page 4 of 13

[Kills fleas on dogs]

[Kills fleas on dogs and puppies 7 weeks or older and 3-10 or 11-20 or 21-55 or over 55 pounds

[lbs]] {weight range depends upon appropriate ml/fl oz package size}

[(Begins/Starts) working through contact]

[[Brand Name] Offers protection against fleas]

[Once per month topical flea treatment for dogs]

[Monthly topical flea treatment for dogs]

[Once-a-month topical treatment for fleas on dogs]

[[Brand Name][This product] is for the treatment and prevention of fleas on dogs]

[Flea control for puppies and dogs over 7 weeks [old][of age] and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[Flea control for puppies and dog 7 weeks [of age] or older] and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[[Once per month][Monthly] topical flea treatment for dogs over 7 weeks [old][of age] and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[[Once per month][Monthly] topical flea treatment for dogs 7 weeks [of age] or older and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[Once-a-month topical treatment for fleas on dogs 7 weeks [of age] or older and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[[Brand Name][This product] is for the treatment and prevention of fleas on dogs over 7 weeks [old][of age] and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[[Brand Name][This product] is for the treatment and prevention of fleas on dogs 7 weeks [of age] or older and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[Prevents and treats flea[s] [infestations]]

[Controls existing infestations by killing adult fleas]

[[Use of Brand Name][Use of this product] kills fleas and may reduce incidence of flea bite hypersensitivity] [and][or] [flea allergy dermatitis] [FAD]]

[[Use of Brand Name][Use of this product] kills fleas and may reduce incidence of [flea bite hypersensitivity] [and][or] flea allergy dermatitis [FAD]]

[Monthly treatment [with Brand Name][with this product] kills fleas and may reduce incidence of [flea bite hypersensitivity] [and][or] flea allergy dermatitis [FAD]]

[Monthly treatment [with Brand Name][with this product] kills fleas and may reduce incidence of flea bite hypersensitivity [and][or] [flea allergy dermatitis] [FAD]]

[May be used year-round for control of fleas]

[Controls fleas, which can serve as an intermediate tapeworm host]

[Controls against [irritating] flea bites]

[Prevents further flea infestations on dogs for 30 days [1 month]]

[Prevents flea re-infestations for 30 days [1 month]]

[IGR Marketing Claims]

[Prevents flea eggs from hatching]

[Prevents flea eggs from developing into [biting] adult fleas]

[Prevents the development of flea eggs into [biting] adult fleas]

[Controls existing flea eggs]

[Kills flea eggs]

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Information in { } is note to reviewer.

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[[Brand Name]][This product] contains Pyriproxyfen [PPF] [an insect growth regulator (IGR)] to kill flea eggs [and protect against reinfestation]]

[Brand Name] contains [an][the] [insect growth regulator] [IGR] [, Pyriproxyfen] [, in addition to imidacloprid]

[Targets multi-stages of flea lifecycle]

[Controls multi-stages of flea lifecycle]

[Kills multiple flea life stages]

[[Brand Name]][This product] is a flea ovicide, larvicide, and adulticide]

[Provides multi-stage flea control]

[Kills [flea eggs and] flea larvae]

[Breaks the flea life cycle]

[Kills flea eggs and flea larvae for up to four [4] weeks][1 month]]

[Prevents multi-stages of the flea life cycle from developing]

[[Brand Name]][This product] inhibits the immature flea life stages (except pupae) from developing and preventing them from becoming [biting] adult[s] [fleas]]

[Monthly treatment controls existing flea eggs and fleas and prevents future infestations]

[Controls existing flea eggs and fleas and prevents future infestations for 30 days [1 month]]

[COMBO Marketing Claims]

[3-way flea protection kills adults, larvae and eggs]

[Kills flea eggs, larvae, and [adult] fleas]

[Kills [adult] fleas, flea eggs, and flea larvae]

[Kills [adult] fleas, flea eggs and flea larvae for up to four [4] weeks][1 month]]

[Kills [adult] fleas, larvae, and eggs [, providing three-way protection]]

[All Other Marketing Claims]

[Apply to [dogs and] puppies over 7 weeks old and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]]
{weight range depends upon appropriate ml/fl oz package size}

[Apply to [dogs and] puppies 7 weeks or older and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]]
{weight range depends upon appropriate ml/fl oz package size}

[From the makers of PetArmor®]

[[Sergeant's] Caring For Your Pets Since 1868]

[Formulated for Dogs and Puppies Over 7 Weeks [Old][of Age] and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[Formulated for Dogs and Puppies 7 Weeks [of Age] or Older and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[Dogs and Puppies over 7 weeks [old][of age] [or] 7 weeks [of age] or older and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[Can be used on puppies over 7 weeks [old][of age] [or] 7 weeks [of age] or older and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[The Only Flea Protection You Need For Your Dog[s] When Applied Monthly!]

[Convenient]

[Easy application]

[Easy to apply product]

[Easy to Use [Application]]

[Convenient, easy to apply topical solution]

[One Step Hassle Free Protection!]

[Waterproof]

[Remains effective, even after [bathing,][shampooing,] water immersion, or exposure to [sunlight]

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[and][or] rain]

[Fragrance[-]free]

[Remains effective even after the dog swims]

[Once a month treatment]

[Apply once every [4 weeks] [month] [30 days]!]

[4 Week Dose!] [1 Month Dose!] [30 Day Dose!]

[For year-round protection, apply [Brand Name][this product] monthly]

[One tube [vial][pipette]] [1 Month Supply]

[Two tube [vials][pipettes]] [2 Month Supply]

[Three tube [vials][pipettes]] [3 Month Supply]

[Four tube [vials][pipettes]] [4 Month Supply]

[Five tube [vials][pipettes]] [5 Month Supply]

[Six tube [vials][pipettes]] [6 Month Supply]

[9 tube [vials][pipettes]] [9 Month Supply]

[12 tube [vials][pipettes]] [12 Month Supply]

[24 tube [vials][pipettes]] [24 Month Supply]

[Direct to skin [tube][vial][applicator][pipette]]

[Easy to Use] [tube][vial][applicator][pipette]

[No-mess [open] [tube][vial][applicator][pipette]]

[Clip-tip design [tube][vial][applicator][pipette][!]]

[Consumer Value Marketing Claims]

[Coupon Inside]

[Save Now!]

[Value Size]

[Club Size]

[Bonus Size]

[Club Pack]

[Great Value]

[Better Value]

[Bonus Pack]

[Bonus Buy]

[[1][2][4][6][7][8][9][X] pack]

[Twin Pack]

[Try Now, Save Later!]

[Z%Free]

[(x) + (x) bonus pack!]

[Buy more and save!]

[Buy X Get Y Free]

[Buy 3 get 1 free]

[(x)% (More) (Free)!]

[33% more free]

[(x) Dose(s) Free!]

[(x) Day(s) (Free)!]

[(x) Month(s) Free!]

[(x) Day(s) of treatment- Free!]

[(x) Tube(s) Free!]

[(x) Applicator(s) Free!]

[(x) Application(s) Free!]

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[33% More Free]

[[New!]] {only for use for 6 months from date of registration}}

{END – FRONT PANEL}

BACK PANEL/SIDE PANEL

Dogs Squeeze On Imidacloprid + Pyriproxyfen

[The active ingredients in [Brand name][this product] are imidacloprid and pyriproxyfen. This product is formulated to control fleas [, flea eggs, and flea larvae] on dogs.] [[Brand Name][This product] kills fleas within 12 hours and prevents further flea infestations for [up to] [[4][four]weeks][[1][one] month][30 days].]

**READ ENTIRE LABEL BEFORE EACH USE.
USE ONLY ON DOGS AND PUPPIES 7 WEEKS OF AGE OR OLDER.**

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and warm water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS. For external use on dogs only. Individual sensitivities, while rare, may occur after using ANY pesticide product for dogs. Do not treat your dog with more than one pesticide product at a time. Over dosing your dog can result in serious illness and even death. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing dogs.

FIRST AID	
If Swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If In Eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If on Skin or Clothing	<ul style="list-style-type: none">• Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-781-4738 for emergency medical treatment information.	
NOTE TO PHYSICIAN	
Treat the patient symptomatically.	

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

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TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.

Restrictions:

- **DO NOT ALLOW CHILDREN TO APPLY PRODUCT.**
- Do not use on animals other than dogs.
- Do not allow your dog to ingest this product.
- Do not reapply for [[four] [4] weeks][30 days]
- Use entire contents of tube [vial][applicator][pipette] on each dog. Do not split one tube [vial][applicator][pipette]s between dogs. Do not use multiple tube [vial][applicator][pipette]s on one dog.
- Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog.
- Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied.
- Do not have contact or allow children to have contact with the treated area until completely dry.

{Side Effects box to be located on label above the cat prohibition icon/text all on the lower right hand side of the back panel}

Side Effects: Monitor your dog after application. [Some dogs may experience temporary startle effects when any product is applied.] Dogs may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe your dog with a mild soap and rinse with large amounts of water. If these or other side effects occur, consult your veterinarian or call 1-800-781-4738. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your dog and continue to monitor your dog for the next 24 hours.

[1.5 cm x 1.5 cm on final or as indicated]

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. Contact your veterinarian if applied to a cat or ingested by a cat.



{OUTER PACKAGING}

How to Open:

1. Remove product tube[s] [vial[s]][applicator[s]][pipette[s]] from the package.
2. Separate one tube [vial][applicator][pipette] from the others. Hold the tube [vial][applicator][pipette] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply:

1. Invert tube [vial][applicator][pipette] over dog and use open end to part dog's hair.
2. Squeeze tube [vial][applicator][pipette] firmly to apply all of the solution to the dog's skin as a spot to the dog's back between the shoulder blades. [or] [from the back of the neck to a point midway between the neck and tail.]

{For cartons containing 0.4 mL (0.014 fl oz) applicator tubes}

Only For Dogs Weighing 3 [-][to] 10 lbs. Do not apply to dogs weighing less than 3 lbs. [including small dogs and puppies, only 7 weeks or older] Apply one

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[tube][vial][applicator][pipette] 0.4 mL (0.014 fl oz) directly to skin [either] [as a spot [on] [to] the dog's back between the shoulder blades] [or] [as a [stripe] [line] starting from the back of the neck to a point midway between the neck and tail].

{For cartons containing 1.0 mL (0.034 fl oz) applicator tube}

Only For Dogs Weighing 11 [-][to] 20 lbs. Do not apply to dogs weighing less than 11 lbs.

Apply one tube[vial][applicator][pipette] 1.0 mL (0.034 fl oz) directly to skin [either] as a spot [on] [to] the dog's back between the shoulder blades [or] [as a [stripe] [line] starting from the back of the neck to a point midway between the neck and tail].

{For cartons containing 2.5 mL (0.085 fl oz) applicator tube}

Only For Dogs Weighing 21 [-][to] 55 lbs. Do not apply to dogs weighing less than 21 lbs.

Apply one tube[vial][applicator][pipette] 2.5 mL (0.085 fl oz) directly to skin [either] as a spot [on] [to] the dog's back between the shoulder blades [or] [as a [stripe] [line] starting from the back of the neck to a point midway between the neck and tail].

{For cartons containing 4.0 mL (0.135 fl oz) applicator tube}

Only For Dogs Weighing 55 lbs. or greater. Do not apply to dogs weighing less than 55 lbs. Do not use two [tube][vial][applicator][pipette]s on dogs greater than 55 lbs. Apply one tube[vial][applicator][pipette] 4.0 mL (0.135 fl oz) directly to skin [either] as a spot [on] [to] the dog's back between the shoulder blades [or] [as a [stripe][line] starting from the back of the neck to a point midway between the neck and tail].

FREQUENCY OF APPLICATION

[Use [Brand Name {or} this product] monthly for control of flea[s] [infestations].] [[Studies show that] [Brand Name {or} This product] kills fleas within 12 hours of application and [lasts {or} protects [for [up to] [[four][4] weeks][30 days][one month].]

[[Brand Name {or} This product] kills reinfesting fleas within [2][two] hours][two hours] and prevents further infestations of fleas [for [up to] [[four][4] weeks][30 days][one month]].]

[[Brand Name {or} This product] [targets multiple flea life stages] [and] [kills flea eggs and larvae before they develop into biting adults].]

[[Brand Name {or} This product] breaks the flea life cycle by killing flea eggs, flea larvae, and adult fleas.]

[If your dog is at high risk for flea reinfestation [, or in a highly infested environment], apply monthly.] [Apply monthly for flea control.]

[[Brand Name {or} This product] is waterproof and remains effective, even after bathing, swimming, or exposure to sunlight [and][or] [rain].] [Allow treated area to dry thoroughly.]

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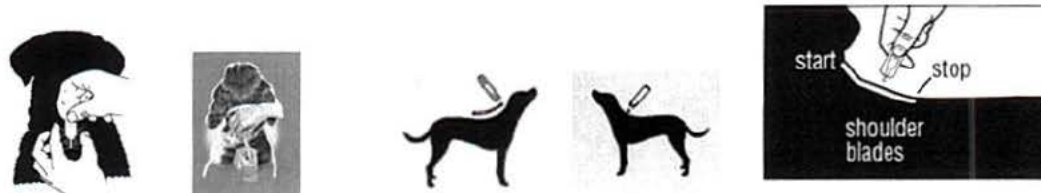
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[How to Apply - May contain graphics illustrating product use, e.g., dog with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling. Refer to following optional graphics.]



STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not remove [tube][vial][applicator][pipette] from the pack until ready to use. Store only in original container in a cool [(below 77°F/[25°C])], dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

CONTAINER DISPOSAL: **If empty:** Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[WARRANTY

Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. The directions for use of this product are believed to adequate and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer. Sergeant's is committed to providing high quality products. To the extent consistent with applicable law, Sergeant's makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Sergeant's, the manufacturer, or the Seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[If you have questions or comments about this product, please write: [Sergeant's][SENTRY][PetArmor®] Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

[Satisfaction Guaranteed][If you are not satisfied, we will make it right with a replacement or refund.]

In Case of Emergency, call: 1-800-781-4738
Non-Emergency, call: 1-800-224-PETS (7387)

[Coupon(s) inside or on outside of box]
[Made in USA With Global Materials]

[Distributed by:] [Manufactured by:]
Sergeant's Pet Care Products, Inc.
Omaha, NE 68138-3710

EPA Reg. No. 2517-RTA
EPA Est. No. XXXXX-XX-XX
[BAR CODE AREA]

{END - BACK/SIDE PANEL}

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{START – ADDITIONAL OPTIONAL PACKAGE COPY OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE OR INSERT}

[Clip. Part. Squeeze.]

[Easier-than-ever applicator lets you *clip* the tip, *part* the fur and *apply* directly to the skin – putting proven flea protection where it needs to be.]

[Application Instructions]

How to Open:

1. Remove product tube[s] [vial[s]][applicator[s]][pipette[s]] from the package.
2. Separate one tube [vial][applicator][pipette] from the others. Hold the tube [vial][applicator][pipette] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply:

1. Invert tube [vial][applicator][pipette] over dog and use open end to part dog's hair.
2. Squeeze tube [vial][applicator][pipette] firmly to apply all of the solution [on] [to] the dog's skin as a spot to the dog's back between the shoulder blades. [or] [from the back of the neck to a point midway between the neck and tail.]

Look at the Label [Easy] 6 Step [Easy] [Spot On] [Squeeze-On] [Topical] Checklist

- [1] Read the label completely and follow directions
- [2] Weigh your dog
- [3] Do NOT use dog products on cats
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate animals after [treatment {or} application] to avoid chance of ingestion
- [6] Do NOT split [tube][vial][applicator][pipette] between dogs][and use the ENTIRE [tube][vial][applicator][pipette] contents]

[Brand Name][This product]

[Monthly reminder card]

[1][2][3][4][5][6][12][24][Month [Treatment] [Application] Tracker][Carecard]

[For year-round protection, apply [Brand Name][this product] monthly.]

[Dog's Name (Empty blank for owner to fill in name)]

[Dog's Weight (Empty blank for owner to fill in name)]

[First][1st][Second][2nd][Third][3rd][Fourth][4th][Fifth][5th][Sixth][6th][Seventh][7th][Eighth]

[8th][Ninth][9th][Tenth][10th][Eleventh][11th][Twelfth][12th]

[Dose] [Treatment] [Application](Empty blank for owner to fill in date)(Date: MM/DD/YY)

[Application Date][Date of Application]

[Calendar stickers with Brand Name]

[Place stickers on your calendar as a reminder to reapply [Brand Name][this product] [in 30 days.]

[Monthly Application Reminder Magnet (image of reminder magnet)]

[Place sticker on your calendar [or refrigerator] to remind yourself to apply [Brand Name][this product] to your dog]

[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days the reminder light will blink, reminding you to reapply [Brand Name][this product]. Press the button

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Information in [] is optional.

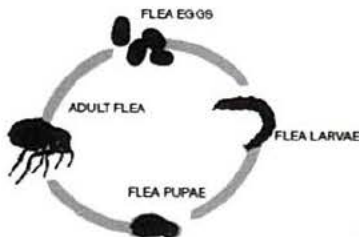
Information in { } is note to reviewer.

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once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

[Each optional graphic below may or may not appear anywhere on the finished label]

	Adult Flea	
	Fleas	
	Flea eggs	
	Flea Larvae	



[Flea life cycle diagram] [Flea Life Cycle]



{non-mandatory optional graphics that may be used in addition to the EPA mandatory icon requirements that currently appear on the label.}

*Refund or replacement of product {text footnote to satisfaction guaranteed graphic}

{END – ADDITIONAL OPTIONAL PACKAGE COPY OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE OR INSERT}

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TUBE/VIAL LABEL

Dogs Squeeze On Imidacloprid + Pyriproxyfen

{Front Label}

{Back Label}

Brand Name {for dogs}

3-10[11-20][21-55][>55] lbs. ≥7 wks

Imidacloprid 9.10%, Pyriproxyfen 0.46%

0.014 fl oz (**or**) 0.034 fl oz (**or**) 0.085 fl oz

(**or**) 0.135 fl oz {label code}



KEEP OUT OF REACH OF CHILDREN

CAUTION Read directions and precautions
on package. Use scissors to open.

EPA REG. No. 2517-RTA

{label code}

{EPA REG No may be on either the front or back label}

{Label code refers to Sergeant's product code number assignment to each product}

{END – TUBE/VIAL LABEL}

Kumar, Rita

From: Kumar, Rita
Sent: Friday, March 11, 2016 3:10 PM
To: Kelly Hoskins (Kelly.Hoskins@perrigo.com)
Cc: 'James Messina'
Subject: New registrations for 2517-175; 2617-176
Attachments: 2517-175-20160310.pdf; 2517-176-20160310.pdf

Dear Kelly: Please see attachments. These actions are now complete. Kindly acknowledge receipt.
Regards,
Rita

